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Anhang 4-G1: Zusatzanalysen, EFFISAYIL ®, Efficacy

1.2 Efficacy and Quality of Life Analysis

1.2.1 Analysis of GPPGA

Table 2.1.1 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	21	60.0	(43.6, 74.4)	0.0002	54.4	(26.0,72.1)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	1	6.7	(1.2, 29.8)	21	13	61.9	(40.9, 79.2)	0.0007	55.2	(20.9,77.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	0	0.0	(0.0, 21.5)	24	15	62.5	(42.7, 78.8)	0.0001	62.5	(35.1,81.2)
Race											
Asian	13	1	7.7	(1.4, 33.3)	16	10	62.5	(38.6, 81.5)	0.0029	54.8	(17.3,79.8)
White	5	0	0.0	(0.0, 43.4)	19	11	57.9	(36.3, 76.9)	0.0394	57.9	(1.8,79.8)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	12	57.1	(36.5, 75.5)	0.0329	57.1	(3.1,79.0)
Asia(ex Japan) + Japan	13	1	7.7	(1.4, 33.3)	14	9	64.3	(38.8, 83.7)	0.0022	56.6	(18.8,82.4)
BMI											
< 25 kg/m2	9	0	0.0	(0.0, 29.9)	15	10	66.7	(41.7, 84.8)	0.0016	66.7	(28.5,88.2)
25 to < 30 kg/m2	6	1	16.7	(3.0, 56.4)	10	6	60.0	(31.3, 83.2)	0.1411	43.3	(-11.5,78.7)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	0	0.0		24	12	50.0				

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Table 2.1.1 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	25.50	(3.71,561.10)	10.80	(2.10,324.59) (1.58,73.95)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	22.75	(2.86,518.90)	9.29	(1.81,268.88) (1.36,63.53)	
Age					NC
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	inf	(7.27, inf)	inf	(2.86, inf)	
Race					NC
Asian	20.00	(2.26,469.94)	8.13	(1.46,230.69) (1.19,55.47)	
White	inf	(1.82, inf)	inf	(1.02, inf)	
Region					NC
Europe + Africa + US	inf	(1.81, inf)	inf	(0.98, inf)	
Asia(ex Japan) + Japan	21.60	(2.30,511.97)	8.36	(1.46,236.47) (1.22,57.18)	
BMI					NC
< 25 kg/m2	inf	(4.67, inf)	inf	(1.67, inf)	
25 to < 30 kg/m2	7.50	(0.62,205.51)	3.60	(0.80,98.38) (0.56,23.11)	
>= 30 kg/m2	inf	(0.60, inf)	inf	(0.59, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.1.1 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	0	0.0	(0.0, 25.9)	21	10	47.6	(28.3, 67.6)	0.0116	47.6	(10.1,70.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	0	0.0	(0.0, 39.0)	13	7	53.8	(29.1, 76.8)	0.0256	53.8	(7.0,80.8)
Baseline GPPGA score											
=3	15	1	6.7	(1.2, 29.8)	28	18	64.3	(45.8, 79.3)	0.0003	57.6	(26.5,77.0)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	1	6.7		29	17	58.6				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	1	10.0	(1.8, 40.4)	20	15	75.0	(53.1, 88.8)	0.0013	65.0	(18.6,85.9)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	1	6.3		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	1	5.6		32	19	59.4				

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Table 2.1.1 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					NC
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	inf	(3.06, inf)	inf	(1.20, inf)	
Baseline GPPGA pustulation subscore					NC
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	inf	(1.74, inf)	inf	(1.10, inf)	
Baseline GPPGA score					NC
=3	25.20	(3.39,564.31)	9.64	(1.81,288.70) (1.42,65.35)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	27.00	(2.94,630.46)	7.50	(1.53,227.78) (1.15,48.98)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.1.1 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.1.1 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Table 2.1.2 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	20	57.1	(40.9, 72.0)	0.0018	46.0	(13.3,66.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	12	57.1	(36.5, 75.5)	0.0079	43.8	(10.2,68.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	14	58.3	(38.8, 75.5)	0.0025	51.2	(17.5,72.7)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0	(0.0, 29.9)	15	10	66.7	(41.7, 84.8)	0.0016	66.7	(28.5,88.2)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	12	50.0				

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Table 2.1.2 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	10.67	(2.25,74.40)	5.14	(1.44,52.13) (1.35,19.60)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	8.67	(1.58,64.88)	4.29	(1.19,38.68) (1.12,16.41)	
Age					0.3231
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	18.20	(2.38,415.48)	8.17	(1.54,236.07) (1.20,55.63)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					NC
< 25 kg/m2	inf	(4.67, inf)	inf	(1.67, inf)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.60, inf)	inf	(0.59, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.1.2 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	1	9.1	(1.6, 37.7)	21	10	47.6	(28.3, 67.6)	0.0412	38.5	(1.1,64.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	1	16.7	(3.0, 56.4)	13	7	53.8	(29.1, 76.8)	0.1750	37.2	(-16.0,71.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	17	60.7	(42.4, 76.4)	0.0051	47.4	(11.6,69.6)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	19	55.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	18	56.3				

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Table 2.1.2 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9108
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	9.09	(1.13,217.30)	5.24	(1.01,144.12) (0.77,35.79)	
Baseline GPPGA pustulation subscore					0.5630
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	5.83	(0.54,157.00)	3.23	(0.70,87.84) (0.50,20.73)	
Baseline GPPGA score					NC
=3	10.05	(1.96,72.58)	4.55	(1.27,54.41) (1.21,17.12)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.1.2 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	16	61.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.3 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	17	48.6	(33.0, 64.4)	0.0112	37.5	(5.8,58.1)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	2	13.3	(3.7, 37.9)	21	10	47.6	(28.3, 67.6)	0.0417	34.3	(2.6,60.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	12	50.0	(31.4, 68.6)	0.0089	42.9	(7.1,65.5)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	10	62.5	(38.6, 81.5)	0.0115	47.1	(10.7,74.8)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	8	38.1	(20.8, 59.1)	0.1849	38.1	(-15.1,62.8)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	9	64.3	(38.8, 83.7)	0.0112	48.9	(9.3,77.9)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	4	40.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	9	37.5				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.3 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.56	(1.61,53.07)	4.37	(1.11,52.13) (1.13,16.87)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	5.91	(1.09,44.76)	3.57	(1.06,38.68) (0.91,14.00)	
Age					0.3189
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	13.00	(1.72,300.12)	7.00	(1.14,196.33) (1.02,48.25)	
Race					NC
Asian	9.17	(1.47,72.54)	4.06	(1.23,43.94) (1.07,15.36)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					NC
Europe + Africa + US	inf	(0.85, inf)	inf	(0.69, inf)	
Asia(ex Japan) + Japan	9.90	(1.50,80.39)	4.18	(1.22,30.59) (1.10,15.85)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.3 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		21	8	38.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	12	54.5	(34.7, 73.1)	0.0148	46.2	(8.9,69.7)
=4	6	1	16.7	(3.0, 56.4)	13	5	38.5	(17.7, 64.5)	0.4859	21.8	(-28.2,58.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	15	53.6	(35.8, 70.5)	0.0168	40.2	(7.0,63.4)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	13	44.8				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	11	55.0	(34.2, 74.2)	0.1143	35.0	(-5.4,65.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	16	47.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	15	46.9				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.3 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4508
<4	13.20	(1.67,308.36)	6.55	(1.18,185.27) (0.96,44.42)	
=4	3.13	(0.29,88.28)	2.31	(0.45,60.18) (0.34,15.69)	
Baseline GPPGA score					NC
=3	7.50	(1.48,54.43)	4.02	(1.08,41.33) (1.06,15.28)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	4.89	(0.82,38.96)	2.75	(0.86,27.08) (0.75,10.11)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.3 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	13	50.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.3 Proportion of patients with GPPGA pustulation subscore of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.4 Proportion of patients with GPPGA pustulation subscore of 0 overall at day 2 - RS (EN-NRI-IE)

	Placebo				Speso 900 mg IV SD					Risk		Odds	
	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	diff.	(95% CI)	ratio	(95% CI)
Overall	18	0	0.0	(0.0, 17.6)	35	4	11.4	(4.5, 26.0)	0.1563	11.4	(-8.2,27.0)	inf	(0.68, inf)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
inf = infinity. NC = not calculable

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Table 2.1.4 Proportion of patients with GPPGA pustulation subscore of 0 overall at day 2 - RS (EN-NRI-IE)

	Risk ratio	(exact 95% CI) (asymp 95% CI)
Overall	inf	(0.54, inf)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
inf = infinity. NC = not calculable

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Table 2.1.5 Proportion of patients with GPPGA pustulation subscore of 0 overall at day 3 - RS (EN-NRI-IE)

	Placebo				Speso 900 mg IV SD					Risk		Odds	
	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	diff.	(95% CI)	ratio	(95% CI)
Overall	18	0	0.0	(0.0, 17.6)	35	11	31.4	(18.6, 48.0)	0.0112	31.4	(5.8,49.3)	inf	(2.84, inf)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
inf = infinity. NC = not calculable

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Table 2.1.5 Proportion of patients with GPPGA pustulation subscore of 0 overall at day 3 - RS (EN-NRI-IE)

	Risk ratio	(exact 95% CI) (asymp 95% CI)
Overall	inf	(1.11, inf)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
inf = infinity. NC = not calculable

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Table 2.1.6 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	17	48.6	(33.0, 64.4)	0.0382	31.9	(2.2,54.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	5	35.7	(16.3, 61.2)	0.3501	35.7	(-35.2,66.5)
Female	15	3	20.0	(7.0, 45.2)	21	12	57.1	(36.5, 75.5)	0.0299	37.1	(2.7,63.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	12	50.0	(31.4, 68.6)	0.0344	35.7	(2.1,60.6)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	8	50.0	(28.0, 72.0)	0.1669	26.9	(-10.2,58.9)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	7	50.0	(26.8, 73.2)	0.1993	26.9	(-11.0,60.2)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	9	60.0	(35.7, 80.2)	0.0276	48.9	(3.6,76.6)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	4	40.0	(16.8, 68.7)	0.8833	6.7	(-45.6,52.2)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	4	40.0	(16.8, 68.7)	0.2779	40.0	(-31.3,75.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	2	16.7		24	9	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.6 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.72	(1.18,22.95)	2.91	(1.02,17.10) (0.98,8.65)	
Sex					NC
Male	inf	(0.37, inf)	inf	(0.40, inf)	
Female	5.33	(1.14,28.40)	2.86	(1.06,15.99) (0.97,8.39)	
Age					0.5700
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	6.00	(1.13,44.82)	3.50	(1.02,31.61) (0.91,13.42)	
Race					NC
Asian	3.33	(0.64,19.32)	2.17	(0.76,11.85) (0.72,6.55)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	3.33	(0.61,20.00)	2.17	(0.70,13.40) (0.71,6.66)	
BMI					NC
< 25 kg/m2	12.00	(1.27,295.27)	5.40	(1.12,151.26) (0.81,35.87)	
25 to < 30 kg/m2	1.33	(0.15,14.54)	1.20	(0.30,8.57) (0.31,4.69)	
>= 30 kg/m2	inf	(0.40, inf)	inf	(0.43, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.1.6 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	6	75.0				
No	11	2	18.2		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	11	50.0	(30.7, 69.3)	0.0245	41.7	(6.6,65.7)
=4	6	2	33.3	(9.7, 70.0)	13	6	46.2	(23.2, 70.9)	0.8190	12.8	(-38.0,54.7)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	15	53.6	(35.8, 70.5)	0.0505	33.6	(0.0,58.6)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	14	48.3				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	4	26.7	(10.9, 52.0)	0.5266	14.2	(-26.5,46.4)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	3	18.8		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	15	46.9				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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inf = infinity. NC = not calculable

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Table 2.1.6 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.2128
<4	11.00	(1.40,258.77)	6.00	(1.10,167.09) (0.88,41.03)	
=4	1.71	(0.21,17.04)	1.38	(0.40,15.12) (0.39,4.95)	
Baseline GPPGA score					NC
=3	4.62	(1.07,23.49)	2.68	(1.00,17.77) (0.92,7.80)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7298
Yes	2.55	(0.25,71.42)	2.13	(0.32,54.74) (0.28,16.02)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.6 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.6 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.7 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	19	54.3	(38.2, 69.5)	0.0162	37.6	(5.8,59.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	12	57.1	(36.5, 75.5)	0.0299	37.1	(2.7,63.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	9	56.3	(33.2, 76.9)	0.0850	33.2	(-4.4,64.1)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	8	57.1	(32.6, 78.6)	0.0906	34.1	(-4.5,67.1)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	3	30.0	(10.8, 60.3)	1.0000	-3.3	(-53.2,43.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	10	41.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.1.7 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.94	(1.48,28.73)	3.26	(1.06,17.74) (1.11,9.56)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	5.33	(1.14,28.40)	2.86	(1.06,15.99) (0.97,8.39)	
Age					0.6265
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	4.29	(0.82,24.72)	2.44	(0.91,11.85) (0.83,7.20)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	4.44	(0.80,26.56)	2.48	(0.88,13.48) (0.83,7.37)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	0.86	(0.09,10.00)	0.90	(0.18,8.56) (0.21,3.94)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.7 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	8	38.1	(20.8, 59.1)	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	5	38.5	(17.7, 64.5)	0.9480	5.1	(-45.0,47.5)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	17	60.7	(42.4, 76.4)	0.0168	40.7	(7.0,64.9)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	16	55.2				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	12	60.0	(38.7, 78.1)	0.0751	40.0	(-1.9,68.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	18	52.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.7 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4271
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					0.1101
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	1.25	(0.15,12.77)	1.15	(0.32,7.12) (0.31,4.34)	
Baseline GPPGA score					NC
=3	6.18	(1.41,31.42)	3.04	(1.08,17.77) (1.06,8.72)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8526
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	6.00	(1.00,47.64)	3.00	(0.94,27.08) (0.83,10.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.7 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	15	57.7			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.7 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.1.8 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	16	45.7	(30.5, 61.8)	0.0163	34.6	(5.8,55.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	2	13.3	(3.7, 37.9)	21	9	42.9	(24.5, 63.5)	0.0727	29.5	(-2.6,56.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	11	45.8	(27.9, 64.9)	0.0221	38.7	(7.1,61.8)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	9	56.3	(33.2, 76.9)	0.0292	40.9	(4.0,69.8)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	8	38.1	(20.8, 59.1)	0.1849	38.1	(-15.1,62.8)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	8	57.1	(32.6, 78.6)	0.0322	41.8	(2.9,71.8)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	8	33.3				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.8 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.74	(1.43,47.48)	4.11	(1.06,39.66) (1.06,15.96)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	4.88	(0.89,37.29)	3.21	(0.92,27.20) (0.81,12.80)	
Age					0.3521
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	11.00	(1.46,255.71)	6.42	(1.08,177.30) (0.92,44.57)	
Race					NC
Asian	7.07	(1.16,56.15)	3.66	(1.06,28.04) (0.95,14.05)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					NC
Europe + Africa + US	inf	(0.85, inf)	inf	(0.69, inf)	
Asia(ex Japan) + Japan	7.33	(1.14,59.66)	3.71	(1.12,30.47) (0.96,14.37)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.8 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	12	54.5	(34.7, 73.1)	0.0148	46.2	(8.9,69.7)
=4	6	1	16.7	(3.0, 56.4)	13	4	30.8	(12.7, 57.6)	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	14	50.0	(32.6, 67.4)	0.0250	36.7	(2.5,59.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	12	41.4				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	10	50.0	(29.9, 70.1)	0.1361	30.0	(-12.0,59.7)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	15	44.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	15	46.9				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.8 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.3661
<4	13.20	(1.67,308.36)	6.55	(1.18,185.27) (0.96,44.42)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					NC
=3	6.50	(1.29,47.35)	3.75	(1.06,41.33) (0.98,14.35)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	4.00	(0.68,32.08)	2.50	(0.79,27.08) (0.67,9.31)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.8 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	12	46.2			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.8 Proportion of patients with GPPGA score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.9 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	14	40.0	(25.6, 56.4)	0.1331	23.3	(-4.4,45.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	4	28.6	(11.7, 54.6)	0.4453	28.6	(-39.3,59.3)
Female	15	3	20.0	(7.0, 45.2)	21	10	47.6	(28.3, 67.6)	0.1384	27.6	(-5.9,55.5)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	9	37.5	(21.2, 57.3)	0.1663	23.2	(-8.9,48.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	8	50.0	(28.0, 72.0)	0.1669	26.9	(-10.2,58.9)
White	5	0	0.0	(0.0, 43.4)	19	6	31.6	(15.4, 54.0)	0.2080	31.6	(-23.9,57.0)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	7	33.3	(17.2, 54.6)	0.1850	33.3	(-20.9,58.0)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	7	50.0	(26.8, 73.2)	0.1993	26.9	(-11.0,60.2)
BMI											
< 25 kg/m2	9	1	11.1		15	7	46.7				
25 to < 30 kg/m2	6	2	33.3		10	4	40.0				
>= 30 kg/m2	3	0	0.0		10	3	30.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	2	16.7		24	7	29.2				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.9 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.33	(0.83,16.40)	2.40	(0.87,17.09) (0.79,7.28)	
Sex					NC
Male	inf	(0.26, inf)	inf	(0.29, inf)	
Female	3.64	(0.78,19.52)	2.38	(0.84,10.52) (0.79,7.20)	
Age					0.7526
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	3.60	(0.67,27.59)	2.63	(0.74,22.92) (0.66,10.47)	
Race					NC
Asian	3.33	(0.64,19.32)	2.17	(0.76,11.85) (0.72,6.55)	
White	inf	(0.62, inf)	inf	(0.54, inf)	
Region					NC
Europe + Africa + US	inf	(0.69, inf)	inf	(0.57, inf)	
Asia(ex Japan) + Japan	3.33	(0.61,20.00)	2.17	(0.70,13.40) (0.71,6.66)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.9 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	6	75.0				
No	11	2	18.2		21	5	23.8				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	9	40.9	(23.3, 61.3)	0.0514	32.6	(-2.5,57.4)
=4	6	2	33.3	(9.7, 70.0)	13	5	38.5	(17.7, 64.5)	0.9480	5.1	(-45.0,47.5)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	12	42.9	(26.5, 60.9)	0.1462	22.9	(-9.8,48.2)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	11	37.9				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	4	26.7	(10.9, 52.0)	0.5266	14.2	(-26.5,46.4)
No	10	2	20.0	(5.7, 51.0)	20	10	50.0	(29.9, 70.1)	0.1361	30.0	(-12.0,59.7)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	3	18.8		34	14	41.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	12	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.9 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.2274
<4	7.62	(0.96,182.43)	4.91	(0.93,132.42) (0.70,34.25)	
=4	1.25	(0.15,12.77)	1.15	(0.32,7.12) (0.31,4.34)	
Baseline GPPGA score					NC
=3	3.00	(0.69,15.47)	2.14	(0.79,12.88) (0.71,6.43)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8972
Yes	2.55	(0.25,71.42)	2.13	(0.32,54.74) (0.28,16.02)	
No	4.00	(0.68,32.08)	2.50	(0.79,27.08) (0.67,9.31)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.9 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.9 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.10 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	19	54.3	(38.2, 69.5)	0.0162	37.6	(5.8,59.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	12	57.1	(36.5, 75.5)	0.0299	37.1	(2.7,63.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	9	56.3	(33.2, 76.9)	0.0850	33.2	(-4.4,64.1)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	8	57.1	(32.6, 78.6)	0.0906	34.1	(-4.5,67.1)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	3	30.0	(10.8, 60.3)	1.0000	-3.3	(-53.2,43.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	10	41.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.1.10 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.94	(1.48,28.73)	3.26	(1.06,17.74) (1.11,9.56)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	5.33	(1.14,28.40)	2.86	(1.06,15.99) (0.97,8.39)	
Age					0.6265
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	4.29	(0.82,24.72)	2.44	(0.91,11.85) (0.83,7.20)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	4.44	(0.80,26.56)	2.48	(0.88,13.48) (0.83,7.37)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	0.86	(0.09,10.00)	0.90	(0.18,8.56) (0.21,3.94)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.10 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	8	38.1	(20.8, 59.1)	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	5	38.5	(17.7, 64.5)	0.9480	5.1	(-45.0,47.5)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	17	60.7	(42.4, 76.4)	0.0168	40.7	(7.0,64.9)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	16	55.2				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	12	60.0	(38.7, 78.1)	0.0751	40.0	(-1.9,68.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	18	52.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.10 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4271
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					0.1101
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	1.25	(0.15,12.77)	1.15	(0.32,7.12) (0.31,4.34)	
Baseline GPPGA score					NC
=3	6.18	(1.41,31.42)	3.04	(1.08,17.77) (1.06,8.72)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8526
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	6.00	(1.00,47.64)	3.00	(0.94,27.08) (0.83,10.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.10 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	15	57.7			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.10 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.11 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	16	45.7	(30.5, 61.8)	0.0163	34.6	(5.8,55.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	2	13.3	(3.7, 37.9)	21	9	42.9	(24.5, 63.5)	0.0727	29.5	(-2.6,56.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	11	45.8	(27.9, 64.9)	0.0221	38.7	(7.1,61.8)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	9	56.3	(33.2, 76.9)	0.0292	40.9	(4.0,69.8)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	8	38.1	(20.8, 59.1)	0.1849	38.1	(-15.1,62.8)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	8	57.1	(32.6, 78.6)	0.0322	41.8	(2.9,71.8)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	8	33.3				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.11 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.74	(1.43,47.48)	4.11	(1.06,39.66) (1.06,15.96)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	4.88	(0.89,37.29)	3.21	(0.92,27.20) (0.81,12.80)	
Age					0.3521
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	11.00	(1.46,255.71)	6.42	(1.08,177.30) (0.92,44.57)	
Race					NC
Asian	7.07	(1.16,56.15)	3.66	(1.06,28.04) (0.95,14.05)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					NC
Europe + Africa + US	inf	(0.85, inf)	inf	(0.69, inf)	
Asia(ex Japan) + Japan	7.33	(1.14,59.66)	3.71	(1.12,30.47) (0.96,14.37)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.11 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	12	54.5	(34.7, 73.1)	0.0148	46.2	(8.9,69.7)
=4	6	1	16.7	(3.0, 56.4)	13	4	30.8	(12.7, 57.6)	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	14	50.0	(32.6, 67.4)	0.0250	36.7	(2.5,59.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	12	41.4				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	10	50.0	(29.9, 70.1)	0.1361	30.0	(-12.0,59.7)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	15	44.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	15	46.9				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.11 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.3661
<4	13.20	(1.67,308.36)	6.55	(1.18,185.27) (0.96,44.42)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					NC
=3	6.50	(1.29,47.35)	3.75	(1.06,41.33) (0.98,14.35)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	4.00	(0.68,32.08)	2.50	(0.79,27.08) (0.67,9.31)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.11 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	12	46.2			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.11 Proportion of patients with GPPGA clear/almost clear (modified) overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.1.12 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	7	20.0	(10.0, 35.9)	0.4666	8.9	(-16.5,28.6)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	2	13.3		21	4	19.0				
Age											
>= 50 years	4	0	0.0		11	0	0.0				
< 50 years	14	2	14.3		24	7	29.2				
Race											
Asian	13	2	15.4		16	2	12.5				
White	5	0	0.0		19	5	26.3				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	2	15.4		14	2	14.3				
BMI											
< 25 kg/m2	9	1	11.1		15	4	26.7				
25 to < 30 kg/m2	6	1	16.7		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	2	16.7		24	2	8.3				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.12 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.00	(0.38,15.33)	1.80	(0.45,17.10) (0.42,7.79)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.12 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	2	25.0			
No	11	2	18.2		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	5	22.7			
=4	6	2	33.3		13	2	15.4			
Baseline GPPGA score										
=3	15	2	13.3		28	6	21.4			
=4	3	0	0.0		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	6	20.7			
Background treatment prior to randomization										
Yes	8	1	12.5		15	0	0.0			
No	10	1	10.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	2	12.5		34	7	20.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	7	21.9			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.12 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.12 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	7	26.9			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.12 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.13 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	10	28.6	(16.3, 45.1)	0.0829	23.0	(-1.5,42.0)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	1	6.7		21	7	33.3				
Age											
>= 50 years	4	0	0.0		11	2	18.2				
< 50 years	14	1	7.1		24	8	33.3				
Race											
Asian	13	1	7.7		16	4	25.0				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	6	28.6				
Asia(ex Japan) + Japan	13	1	7.7		14	4	28.6				
BMI											
< 25 kg/m2	9	0	0.0		15	5	33.3				
25 to < 30 kg/m2	6	1	16.7		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	6	25.0				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.13 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.80	(0.97,156.99)	5.14	(0.91,137.23) (0.71,37.08)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.13 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	4	50.0			
No	11	1	9.1		21	5	23.8			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	9	40.9			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7	(1.2, 29.8)	28	10	35.7	(20.7, 54.2)	0.0505	29.0 (0.0,50.7)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	10	34.5			
Background treatment prior to randomization										
Yes	8	0	0.0		15	5	33.3			
No	10	1	10.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	1	6.3		34	9	26.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	10	31.3			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.13 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	7.78	(1.06,181.50)	5.36	(0.94,144.45) (0.76,37.94)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.13 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	8	30.8			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.13 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.14 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	10	28.6	(16.3, 45.1)	0.1771	17.5 (-8.8,37.8)
Sex										
Male	3	0	0.0		14	4	28.6			
Female	15	2	13.3		21	6	28.6			
Age										
>= 50 years	4	1	25.0		11	3	27.3			
< 50 years	14	1	7.1		24	7	29.2			
Race										
Asian	13	2	15.4		16	4	25.0			
White	5	0	0.0		19	6	31.6			
Region										
Europe + Africa + US	5	0	0.0		21	7	33.3			
Asia(ex Japan) + Japan	13	2	15.4		14	3	21.4			
BMI										
< 25 kg/m2	9	0	0.0		15	6	40.0			
25 to < 30 kg/m2	6	2	33.3		10	1	10.0			
>= 30 kg/m2	3	0	0.0		10	3	30.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	3	60.0			
No	12	1	8.3		24	5	20.8			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.14 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.20	(0.66,23.45)	2.57	(0.72,27.91) (0.63,10.51)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.14 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	4	50.0				
No	11	1	9.1		21	4	19.0				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3		22	8	36.4				
=4	6	1	16.7		13	2	15.4				
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	9	32.1	(17.9, 50.7)	0.3199	18.8	(-10.7,42.5)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	1	16.7				
No	15	2	13.3		29	9	31.0				
Background treatment prior to randomization											
Yes	8	0	0.0		15	4	26.7				
No	10	2	20.0		20	6	30.0				
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		34	10	29.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	9	28.1				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.14 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	3.08	(0.59,23.32)	2.41	(0.69,22.04) (0.60,9.76)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.14 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	7	26.9			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.14 Proportion of patients with GPPGA erythema subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.15 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	8	22.9	(12.1, 39.0)	0.7741	6.2	(-20.3,27.6)
Sex											
Male	3	0	0.0		14	2	14.3				
Female	15	3	20.0		21	6	28.6				
Age											
>= 50 years	4	1	25.0		11	3	27.3				
< 50 years	14	2	14.3		24	5	20.8				
Race											
Asian	13	3	23.1		16	4	25.0				
White	5	0	0.0		19	4	21.1				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	3	23.1		14	3	21.4				
BMI											
< 25 kg/m2	9	1	11.1		15	4	26.7				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	1	20.0				
No	12	2	16.7		24	5	20.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.15 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.48	(0.34,7.76)	1.37	(0.44,7.64) (0.41,4.55)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.15 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	2	25.0			
No	11	2	18.2		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	6	27.3			
=4	6	2	33.3		13	2	15.4			
Baseline GPPGA score										
=3	15	3	20.0	(7.0, 45.2)	28	8	28.6	(15.3, 47.1)	0.7551	8.6 (-22.2,33.7)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	3	20.0		29	7	24.1			
Background treatment prior to randomization										
Yes	8	1	12.5		15	4	26.7			
No	10	2	20.0		20	4	20.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	3	18.8		34	8	23.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	3	16.7		32	7	21.9			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.15 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	1.60	(0.35,8.64)	1.43	(0.47,7.92) (0.44,4.60)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.15 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	6	23.1			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.15 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.1.16 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	18	51.4	(35.6, 67.0)	0.0235	34.8	(4.3,56.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	11	52.4	(32.4, 71.7)	0.0586	32.4	(-1.2,59.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	8	50.0	(28.0, 72.0)	0.1669	26.9	(-10.2,58.9)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	7	50.0	(26.8, 73.2)	0.1993	26.9	(-11.0,60.2)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	9	60.0	(35.7, 80.2)	0.0276	48.9	(3.6,76.6)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	3	30.0	(10.8, 60.3)	1.0000	-3.3	(-53.2,43.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	9	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.16 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.29	(1.33,25.66)	3.09	(1.06,17.10) (1.05,9.10)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	4.40	(0.94,23.48)	2.62	(0.97,11.76) (0.88,7.80)	
Age					0.5228
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	3.33	(0.64,19.32)	2.17	(0.76,11.85) (0.72,6.55)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	3.33	(0.61,20.00)	2.17	(0.70,13.40) (0.71,6.66)	
BMI					NC
< 25 kg/m2	12.00	(1.27,295.27)	5.40	(1.12,151.26) (0.81,35.87)	
25 to < 30 kg/m2	0.86	(0.09,10.00)	0.90	(0.18,8.56) (0.21,3.94)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.1.16 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	2	18.2	(5.1, 47.7)	21	8	38.1	(20.8, 59.1)	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	4	30.8	(12.7, 57.6)	1.0000	-2.6	(-51.7,40.0)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	17	60.7	(42.4, 76.4)	0.0168	40.7	(7.0,64.9)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	15	51.7				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	11	55.0	(34.2, 74.2)	0.1143	35.0	(-5.4,65.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	17	53.1				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.1.16 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5124
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					0.0792
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	0.89	(0.11,9.49)	0.92	(0.23,6.67) (0.23,3.72)	
Baseline GPPGA score					NC
=3	6.18	(1.41,31.42)	3.04	(1.08,17.77) (1.06,8.72)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7956
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	4.89	(0.82,38.96)	2.75	(0.86,27.08) (0.75,10.11)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.1.16 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.1.16 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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Table 2.1.17 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	15	42.9	(28.0, 59.1)	0.0235	31.7	(2.2,52.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	2	13.3	(3.7, 37.9)	21	8	38.1	(20.8, 59.1)	0.1384	24.8	(-6.9,51.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	10	41.7	(24.5, 61.2)	0.0301	34.5	(2.1,58.1)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	9	56.3	(33.2, 76.9)	0.0292	40.9	(4.0,69.8)
White	5	0	0.0	(0.0, 43.4)	19	6	31.6	(15.4, 54.0)	0.2080	31.6	(-23.9,57.0)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	7	33.3	(17.2, 54.6)	0.1850	33.3	(-20.9,58.0)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	8	57.1	(32.6, 78.6)	0.0322	41.8	(2.9,71.8)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	1	8.3		24	10	41.7				

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Table 2.1.17 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.00	(1.27,42.46)	3.86	(1.02,39.66) (0.99,15.05)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	4.00	(0.72,31.00)	2.86	(0.77,23.60) (0.70,11.59)	
Age					0.3909
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	9.29	(1.23,217.63)	5.83	(1.02,158.80) (0.83,40.88)	
Race					NC
Asian	7.07	(1.16,56.15)	3.66	(1.06,28.04) (0.95,14.05)	
White	inf	(0.62, inf)	inf	(0.54, inf)	
Region					NC
Europe + Africa + US	inf	(0.69, inf)	inf	(0.57, inf)	
Asia(ex Japan) + Japan	7.33	(1.14,59.66)	3.71	(1.12,30.47) (0.96,14.37)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.1.17 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	4	50.0				
No	11	1	9.1		21	8	38.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	11	50.0	(30.7, 69.3)	0.0245	41.7	(6.6,65.7)
=4	6	1	16.7	(3.0, 56.4)	13	4	30.8	(12.7, 57.6)	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	12	42.9	(26.5, 60.9)	0.0874	29.5	(-2.0,53.0)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	2	13.3		29	12	41.4				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	9	45.0	(25.8, 65.8)	0.3035	25.0	(-14.9,55.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	14	41.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	14	43.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.17 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4009
<4	11.00	(1.40,258.77)	6.00	(1.10,167.09) (0.88,41.03)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					NC
=3	4.88	(0.96,35.90)	3.21	(0.94,29.05) (0.83,12.51)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	3.27	(0.55,26.49)	2.25	(0.69,17.96) (0.59,8.52)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.17 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.1.17 Proportion of patients with GPPGA scaling subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.18 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	22	62.9	(46.3, 76.8)	0.0005	51.7	(21.5,70.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	14	66.7	(45.4, 82.8)	0.0021	53.3	(20.9,76.3)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	16	66.7	(46.7, 82.0)	0.0005	59.5	(23.0,79.5)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	11	57.9	(36.3, 76.9)	0.0394	57.9	(1.8,79.8)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	12	57.1	(36.5, 75.5)	0.0329	57.1	(3.1,79.0)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0	(0.0, 29.9)	15	10	66.7	(41.7, 84.8)	0.0016	66.7	(28.5,88.2)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	6	60.0	(31.3, 83.2)	0.4303	26.7	(-26.3,69.1)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	13	54.2				

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Table 2.1.18 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	13.54	(2.82,94.24)	5.66	(1.69,65.20) (1.49,21.42)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	13.00	(2.29,97.10)	5.00	(1.48,55.17) (1.33,18.81)	
Age					0.2753
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	26.00	(3.31,588.27)	9.33	(1.94,278.26) (1.38,63.01)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.82, inf)	inf	(1.02, inf)	
Region					NC
Europe + Africa + US	inf	(1.81, inf)	inf	(0.98, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					NC
< 25 kg/m2	inf	(4.67, inf)	inf	(1.67, inf)	
25 to < 30 kg/m2	3.00	(0.33,31.20)	1.80	(0.55,19.53) (0.52,6.22)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.1.18 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	1	9.1	(1.6, 37.7)	21	11	52.4	(32.4, 71.7)	0.0222	43.3	(3.8,69.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	15	68.2	(47.3, 83.6)	0.0010	59.8	(21.1,80.7)
=4	6	1	16.7	(3.0, 56.4)	13	7	53.8	(29.1, 76.8)	0.1750	37.2	(-16.0,71.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	19	67.9	(49.3, 82.1)	0.0014	54.5	(20.9,75.5)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	18	62.1				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	2	20.0	(5.7, 51.0)	20	15	75.0	(53.1, 88.8)	0.0088	55.0	(11.5,81.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	21	61.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	20	62.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.18 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9448
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	11.00	(1.36,260.77)	5.76	(1.10,161.22) (0.85,39.02)	
Baseline GPPGA pustulation subscore					0.4930
<4	23.57	(2.85,541.70)	8.18	(1.75,243.60) (1.23,54.60)	
=4	5.83	(0.54,157.00)	3.23	(0.70,87.84) (0.50,20.73)	
Baseline GPPGA score					NC
=3	13.72	(2.61,99.10)	5.09	(1.62,54.40) (1.37,18.96)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	12.00	(1.84,96.20)	3.75	(1.14,38.64) (1.06,13.29)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.1.18 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	18	69.2			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.1.18 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Table 2.1.19 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	21	60.0	(43.6, 74.4)	0.0052	43.3	(9.6,64.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	3	20.0	(7.0, 45.2)	21	13	61.9	(40.9, 79.2)	0.0200	41.9	(8.1,67.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	15	62.5	(42.7, 78.8)	0.0069	48.2	(12.2,71.4)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	11	68.8	(44.4, 85.8)	0.0181	45.7	(7.4,74.3)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	10	71.4	(45.4, 88.3)	0.0154	48.4	(8.7,77.3)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	12	50.0				

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Table 2.1.19 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.50	(1.86,36.24)	3.60	(1.27,27.91) (1.24,10.47)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	6.50	(1.37,34.65)	3.10	(1.12,22.60) (1.07,8.99)	
Age					0.5385
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	10.00	(1.85,73.97)	4.38	(1.21,45.03) (1.17,16.38)	
Race					NC
Asian	7.33	(1.33,43.09)	2.98	(1.14,12.38) (1.05,8.48)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	8.33	(1.40,51.74)	3.10	(1.21,13.49) (1.09,8.81)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.1.19 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	10	47.6	(28.3, 67.6)	0.1280	29.4	(-8.2,58.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	7	53.8	(29.1, 76.8)	0.4869	20.5	(-30.9,61.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	18	64.3	(45.8, 79.3)	0.0071	44.3	(7.0,68.0)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		29	17	58.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	19	59.4				

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inf = infinity. NC = not calculable

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Table 2.1.19 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5439
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	4.09	(0.72,32.21)	2.62	(0.79,28.37) (0.69,9.92)	
Baseline GPPGA pustulation subscore					0.1799
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	2.33	(0.29,22.83)	1.62	(0.53,15.12) (0.47,5.57)	
Baseline GPPGA score					NC
=3	7.20	(1.63,36.65)	3.21	(1.13,17.77) (1.13,9.18)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9561
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.1.19 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.19 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.20 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	20	57.1	(40.9, 72.0)	0.0018	46.0	(13.3,66.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	12	57.1	(36.5, 75.5)	0.0079	43.8	(10.2,68.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	14	58.3	(38.8, 75.5)	0.0025	51.2	(17.5,72.7)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0		15	9	60.0				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	11	45.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.20 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	10.67	(2.25,74.40)	5.14	(1.44,52.13) (1.35,19.60)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	8.67	(1.58,64.88)	4.29	(1.19,38.68) (1.12,16.41)	
Age					0.3231
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	18.20	(2.38,415.48)	8.17	(1.54,236.07) (1.20,55.63)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.20 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	1	16.7	(3.0, 56.4)	13	6	46.2	(23.2, 70.9)	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	17	60.7	(42.4, 76.4)	0.0051	47.4	(11.6,69.6)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	19	55.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.20 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9365
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.4577
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					NC
=3	10.05	(1.96,72.58)	4.55	(1.27,54.41) (1.21,17.12)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.20 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	16	61.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.1.20 Proportion of patients with GPPGA pustulation subscore of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.2 Analysis of GPPASI

Table 2.2.1 Proportion of patients with GPPASI 50 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	6	33.3	(16.3, 56.3)	35	17	48.6	(33.0, 64.4)	0.3794	15.2	(-14.4,41.4)
Sex											
Male	3	1	33.3	(6.1, 79.2)	14	6	42.9	(21.4, 67.4)	1.0000	9.5	(-52.2,56.4)
Female	15	5	33.3	(15.2, 58.3)	21	11	52.4	(32.4, 71.7)	0.4045	19.0	(-15.9,49.5)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	4	36.4	(15.2, 64.6)	0.9287	11.4	(-47.2,55.4)
< 50 years	14	5	35.7	(16.3, 61.2)	24	13	54.2	(35.1, 72.1)	0.4302	18.5	(-17.4,48.7)
Race											
Asian	13	5	38.5	(17.7, 64.5)	16	8	50.0	(28.0, 72.0)	0.6179	11.5	(-25.7,46.5)
White	5	1	20.0	(3.6, 62.4)	19	9	47.4	(27.3, 68.3)	0.3749	27.4	(-26.5,61.3)
Region											
Europe + Africa + US	5	1	20.0	(3.6, 62.4)	21	10	47.6	(28.3, 67.6)	0.3830	27.6	(-26.3,60.3)
Asia(ex Japan) + Japan	13	5	38.5	(17.7, 64.5)	14	7	50.0	(26.8, 73.2)	0.6332	11.5	(-27.1,49.2)
BMI											
< 25 kg/m2	9	2	22.2	(6.3, 54.7)	15	8	53.3	(30.1, 75.2)	0.1781	31.1	(-11.7,64.1)
25 to < 30 kg/m2	6	4	66.7	(30.0, 90.3)	10	5	50.0	(23.7, 76.3)	0.7018	-16.7	(-61.0,35.7)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	4	40.0	(16.8, 68.7)	0.2779	40.0	(-31.3,75.5)
Mutation status IL36RN											
Yes	2	1	50.0		5	4	80.0				
No	12	3	25.0		24	9	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.1 Proportion of patients with GPPASI 50 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.89	(0.57,6.51)	1.46	(0.72,5.11) (0.70,3.04)	
Sex					0.8359
Male	1.50	(0.09,51.21)	1.29	(0.33,34.04) (0.23,7.11)	
Female	2.20	(0.54,9.24)	1.57	(0.71,5.25) (0.69,3.58)	
Age					0.9678
>= 50 years	1.71	(0.13,55.79)	1.45	(0.26,37.76) (0.22,9.43)	
< 50 years	2.13	(0.53,8.79)	1.52	(0.73,6.16) (0.69,3.35)	
Race					0.5572
Asian	1.60	(0.35,7.53)	1.30	(0.54,3.65) (0.56,3.02)	
White	3.60	(0.35,98.27)	2.37	(0.56,64.70) (0.39,14.56)	
Region					0.5542
Europe + Africa + US	3.64	(0.36,98.33)	2.38	(0.61,65.60) (0.39,14.54)	
Asia(ex Japan) + Japan	1.60	(0.33,7.88)	1.30	(0.53,3.58) (0.55,3.09)	
BMI					NC
< 25 kg/m2	4.00	(0.60,34.15)	2.40	(0.76,19.72) (0.65,8.90)	
25 to < 30 kg/m2	0.50	(0.05,4.47)	0.75	(0.26,2.19) (0.32,1.74)	
>= 30 kg/m2	inf	(0.40, inf)	inf	(0.43, inf)	
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.1 Proportion of patients with GPPASI 50 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	2	33.3	(9.7, 70.0)	8	5	62.5	(30.6, 86.3)	0.4163	29.2	(-27.0,73.1)
No	11	4	36.4	(15.2, 64.6)	21	8	38.1	(20.8, 59.1)	0.9985	1.7	(-35.7,35.8)
Baseline GPPGA pustulation subscore											
<4	12	2	16.7	(4.7, 44.8)	22	10	45.5	(26.9, 65.3)	0.1411	28.8	(-7.2,57.1)
=4	6	4	66.7	(30.0, 90.3)	13	7	53.8	(29.1, 76.8)	0.8190	-12.8	(-54.7,38.0)
Baseline GPPGA score											
=3	15	5	33.3	(15.2, 58.3)	28	14	50.0	(32.6, 67.4)	0.4089	16.7	(-15.7,45.3)
=4	3	1	33.3	(6.1, 79.2)	7	3	42.9	(15.8, 75.0)	0.9428	9.5	(-58.8,65.2)
Baseline plaque psoriasis											
Yes	3	2	66.7		6	4	66.7				
No	15	4	26.7		29	13	44.8				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	3	20.0	(7.0, 45.2)	0.8258	7.5	(-32.7,39.5)
No	10	5	50.0	(23.7, 76.3)	20	14	70.0	(48.1, 85.5)	0.3645	20.0	(-18.0,55.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	6	37.5		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	6	33.3		32	15	46.9				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.1 Proportion of patients with GPPASI 50 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4685
Yes	3.33	(0.32,37.36)	1.88	(0.56,11.57) (0.54,6.56)	
No	1.08	(0.23,5.41)	1.05	(0.40,4.80) (0.40,2.72)	
Baseline GPPGA pustulation subscore					0.1224
<4	4.17	(0.75,32.32)	2.73	(0.79,29.55) (0.71,10.47)	
=4	0.58	(0.06,4.71)	0.81	(0.36,2.41) (0.38,1.72)	
Baseline GPPGA score					0.8791
=3	2.00	(0.53,7.89)	1.50	(0.69,7.12) (0.67,3.36)	
=4	1.50	(0.07,58.21)	1.29	(0.23,33.89) (0.21,7.89)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9054
Yes	1.75	(0.15,52.28)	1.60	(0.19,41.31) (0.20,12.99)	
No	2.33	(0.45,11.78)	1.40	(0.76,5.54) (0.71,2.77)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.1 Proportion of patients with GPPASI 50 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	6	37.5		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.1 Proportion of patients with GPPASI 50 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.2 Proportion of patients with GPPASI 50 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	21	60.0	(43.6, 74.4)	0.0052	43.3	(9.6,64.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	3	20.0	(7.0, 45.2)	21	13	61.9	(40.9, 79.2)	0.0200	41.9	(8.1,67.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	15	62.5	(42.7, 78.8)	0.0069	48.2	(12.2,71.4)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	11	68.8	(44.4, 85.8)	0.0181	45.7	(7.4,74.3)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	10	71.4	(45.4, 88.3)	0.0154	48.4	(8.7,77.3)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	12	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.2.2 Proportion of patients with GPPASI 50 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.50	(1.86,36.24)	3.60	(1.27,27.91) (1.24,10.47)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	6.50	(1.37,34.65)	3.10	(1.12,22.60) (1.07,8.99)	
Age					0.5385
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	10.00	(1.85,73.97)	4.38	(1.21,45.03) (1.17,16.38)	
Race					NC
Asian	7.33	(1.33,43.09)	2.98	(1.14,12.38) (1.05,8.48)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	8.33	(1.40,51.74)	3.10	(1.21,13.49) (1.09,8.81)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.2 Proportion of patients with GPPASI 50 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	10	47.6	(28.3, 67.6)	0.1280	29.4	(-8.2,58.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	7	53.8	(29.1, 76.8)	0.4869	20.5	(-30.9,61.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	18	64.3	(45.8, 79.3)	0.0071	44.3	(7.0,68.0)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		29	17	58.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	19	59.4				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.2 Proportion of patients with GPPASI 50 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5439
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	4.09	(0.72,32.21)	2.62	(0.79,28.37) (0.69,9.92)	
Baseline GPPGA pustulation subscore					0.1799
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	2.33	(0.29,22.83)	1.62	(0.53,15.12) (0.47,5.57)	
Baseline GPPGA score					NC
=3	7.20	(1.63,36.65)	3.21	(1.13,17.77) (1.13,9.18)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9561
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.2 Proportion of patients with GPPASI 50 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.2.2 Proportion of patients with GPPASI 50 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.2.3 Proportion of patients with GPPASI 50 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	20	57.1	(40.9, 72.0)	0.0018	46.0	(13.3,66.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	12	57.1	(36.5, 75.5)	0.0079	43.8	(10.2,68.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	14	58.3	(38.8, 75.5)	0.0025	51.2	(17.5,72.7)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0		15	9	60.0				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	11	45.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.3 Proportion of patients with GPPASI 50 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	10.67	(2.25,74.40)	5.14	(1.44,52.13) (1.35,19.60)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	8.67	(1.58,64.88)	4.29	(1.19,38.68) (1.12,16.41)	
Age					0.3231
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	18.20	(2.38,415.48)	8.17	(1.54,236.07) (1.20,55.63)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.2.3 Proportion of patients with GPPASI 50 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	1	16.7	(3.0, 56.4)	13	6	46.2	(23.2, 70.9)	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	17	60.7	(42.4, 76.4)	0.0051	47.4	(11.6,69.6)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	19	55.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.3 Proportion of patients with GPPASI 50 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9365
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.4577
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					NC
=3	10.05	(1.96,72.58)	4.55	(1.27,54.41) (1.21,17.12)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.2.3 Proportion of patients with GPPASI 50 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	16	61.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.3 Proportion of patients with GPPASI 50 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.4 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	7	38.9	(20.3, 61.4)	35	25	71.4	(54.9, 83.7)	0.0266	32.5	(2.2,57.9)
Sex											
Male	3	1	33.3	(6.1, 79.2)	14	11	78.6	(52.4, 92.4)	0.1936	45.2	(-16.6,85.6)
Female	15	6	40.0	(19.8, 64.3)	21	14	66.7	(45.4, 82.8)	0.1384	26.7	(-7.2,57.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	6	42.9	(21.4, 67.4)	24	19	79.2	(59.5, 90.8)	0.0301	36.3	(2.1,64.8)
Race											
Asian	13	4	30.8	(12.7, 57.6)	16	11	68.8	(44.4, 85.8)	0.0493	38.0	(0.1,68.4)
White	5	3	60.0	(23.1, 88.2)	19	14	73.7	(51.2, 88.2)	0.7314	13.7	(-28.7,60.8)
Region											
Europe + Africa + US	5	3	60.0	(23.1, 88.2)	21	15	71.4	(50.0, 86.2)	1.0000	11.4	(-29.9,58.8)
Asia(ex Japan) + Japan	13	4	30.8	(12.7, 57.6)	14	10	71.4	(45.4, 88.3)	0.0534	40.7	(-0.5,71.6)
BMI											
< 25 kg/m2	9	4	44.4	(18.9, 73.3)	15	11	73.3	(48.0, 89.1)	0.2024	28.9	(-13.3,65.1)
25 to < 30 kg/m2	6	3	50.0	(18.8, 81.2)	10	7	70.0	(39.7, 89.2)	0.7015	20.0	(-31.0,65.4)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	7	70.0	(39.7, 89.2)	0.0524	70.0	(-0.6,94.3)
Mutation status IL36RN											
Yes	2	1	50.0		5	5	100.0				
No	12	5	41.7		24	15	62.5				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.4 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.93	(1.15,13.41)	1.84	(1.02,6.22) (0.99,3.40)	
Sex					0.7001
Male	7.33	(0.38,233.53)	2.36	(0.78,70.99) (0.46,11.95)	
Female	3.00	(0.73,12.38)	1.67	(0.87,4.41) (0.84,3.32)	
Age					0.8631
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	5.07	(1.14,22.55)	1.85	(1.02,6.42) (0.98,3.50)	
Race					0.3142
Asian	4.95	(0.97,25.77)	2.23	(0.98,11.78) (0.93,5.39)	
White	1.87	(0.17,15.96)	1.23	(0.67,8.69) (0.57,2.64)	
Region					0.2617
Europe + Africa + US	1.67	(0.16,13.80)	1.19	(0.65,7.87) (0.55,2.56)	
Asia(ex Japan) + Japan	5.63	(1.02,31.50)	2.32	(0.99,13.20) (0.96,5.60)	
BMI					NC
< 25 kg/m2	3.44	(0.55,21.21)	1.65	(0.80,8.68) (0.75,3.64)	
25 to < 30 kg/m2	2.33	(0.25,21.35)	1.40	(0.58,8.53) (0.57,3.43)	
>= 30 kg/m2	inf	(1.26, inf)	inf	(0.90, inf)	
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.4 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	2	33.3	(9.7, 70.0)	8	7	87.5	(52.9, 97.8)	0.0675	54.2	(-3.4,88.9)
No	11	5	45.5	(21.3, 72.0)	21	13	61.9	(40.9, 79.2)	0.4405	16.5	(-21.0,51.6)
Baseline GPPGA pustulation subscore											
<4	12	3	25.0	(8.9, 53.2)	22	16	72.7	(51.8, 86.8)	0.0148	47.7	(8.9,74.1)
=4	6	4	66.7	(30.0, 90.3)	13	9	69.2	(42.4, 87.3)	1.0000	2.6	(-40.0,51.7)
Baseline GPPGA score											
=3	15	5	33.3	(15.2, 58.3)	28	21	75.0	(56.6, 87.3)	0.0118	41.7	(7.0,67.7)
=4	3	2	66.7	(20.8, 93.9)	7	4	57.1	(25.0, 84.2)	0.9428	-9.5	(-65.2,58.8)
Baseline plaque psoriasis											
Yes	3	1	33.3		6	5	83.3				
No	15	6	40.0		29	20	69.0				
Background treatment prior to randomization											
Yes	8	3	37.5	(13.7, 69.4)	15	9	60.0	(35.7, 80.2)	0.4218	22.5	(-22.4,60.3)
No	10	4	40.0	(16.8, 68.7)	20	16	80.0	(58.4, 91.9)	0.0383	40.0	(2.0,71.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	7	43.8		34	24	70.6				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	7	38.9		32	22	68.8				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.4 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.3483
Yes	14.00	(0.87,389.38)	2.63	(0.95,24.25) (0.82,8.39)	
No	1.95	(0.42,9.05)	1.36	(0.69,5.09) (0.66,2.82)	
Baseline GPPGA pustulation subscore					0.0967
<4	8.00	(1.55,44.70)	2.91	(1.10,18.04) (1.06,8.01)	
=4	1.13	(0.11,9.52)	1.04	(0.52,4.07) (0.53,2.03)	
Baseline GPPGA score					0.1360
=3	6.00	(1.47,24.79)	2.25	(1.08,7.92) (1.07,4.75)	
=4	0.67	(0.02,13.38)	0.86	(0.27,5.97) (0.31,2.39)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7291
Yes	2.50	(0.40,16.54)	1.60	(0.66,7.75) (0.60,4.29)	
No	6.00	(1.05,34.21)	2.00	(1.03,7.33) (0.91,4.41)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.4 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	7	43.8		26	21	80.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.4 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.5 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	21	60.0	(43.6, 74.4)	0.0052	43.3	(9.6,64.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	3	20.0	(7.0, 45.2)	21	13	61.9	(40.9, 79.2)	0.0200	41.9	(8.1,67.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	15	62.5	(42.7, 78.8)	0.0069	48.2	(12.2,71.4)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	11	68.8	(44.4, 85.8)	0.0181	45.7	(7.4,74.3)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	10	71.4	(45.4, 88.3)	0.0154	48.4	(8.7,77.3)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	12	50.0				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.5 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.50	(1.86,36.24)	3.60	(1.27,27.91) (1.24,10.47)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	6.50	(1.37,34.65)	3.10	(1.12,22.60) (1.07,8.99)	
Age					0.5385
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	10.00	(1.85,73.97)	4.38	(1.21,45.03) (1.17,16.38)	
Race					NC
Asian	7.33	(1.33,43.09)	2.98	(1.14,12.38) (1.05,8.48)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	8.33	(1.40,51.74)	3.10	(1.21,13.49) (1.09,8.81)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.5 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	10	47.6	(28.3, 67.6)	0.1280	29.4	(-8.2,58.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	7	53.8	(29.1, 76.8)	0.4869	20.5	(-30.9,61.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	18	64.3	(45.8, 79.3)	0.0071	44.3	(7.0,68.0)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		29	17	58.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	19	59.4				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.5 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5439
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	4.09	(0.72,32.21)	2.62	(0.79,28.37) (0.69,9.92)	
Baseline GPPGA pustulation subscore					0.1799
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	2.33	(0.29,22.83)	1.62	(0.53,15.12) (0.47,5.57)	
Baseline GPPGA score					NC
=3	7.20	(1.63,36.65)	3.21	(1.13,17.77) (1.13,9.18)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9561
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.5 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.5 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.6 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	20	57.1	(40.9, 72.0)	0.0018	46.0	(13.3,66.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	12	57.1	(36.5, 75.5)	0.0079	43.8	(10.2,68.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	14	58.3	(38.8, 75.5)	0.0025	51.2	(17.5,72.7)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0		15	9	60.0				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	11	45.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.6 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	10.67	(2.25,74.40)	5.14	(1.44,52.13) (1.35,19.60)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	8.67	(1.58,64.88)	4.29	(1.19,38.68) (1.12,16.41)	
Age					0.3231
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	18.20	(2.38,415.48)	8.17	(1.54,236.07) (1.20,55.63)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.6 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	1	16.7	(3.0, 56.4)	13	6	46.2	(23.2, 70.9)	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	17	60.7	(42.4, 76.4)	0.0051	47.4	(11.6,69.6)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	19	55.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.6 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9365
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.4577
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					NC
=3	10.05	(1.96,72.58)	4.55	(1.27,54.41) (1.21,17.12)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.2.6 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	16	61.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.6 Proportion of patients with GPPASI 50 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.7 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	12	34.3	(20.8, 50.8)	0.3094	17.6	(-10.4,39.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	4	28.6	(11.7, 54.6)	0.4453	28.6	(-39.3,59.3)
Female	15	3	20.0	(7.0, 45.2)	21	8	38.1	(20.8, 59.1)	0.4045	18.1	(-14.3,46.6)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	2	18.2	(5.1, 47.7)	0.9287	-6.8	(-62.4,37.0)
< 50 years	14	2	14.3	(4.0, 39.9)	24	10	41.7	(24.5, 61.2)	0.0997	27.4	(-6.8,52.9)
Race											
Asian	13	3	23.1		16	6	37.5				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	7	33.3				
Asia(ex Japan) + Japan	13	3	23.1		14	5	35.7				
BMI											
< 25 kg/m2	9	1	11.1		15	7	46.7				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	2	16.7		24	6	25.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.7 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.61	(0.64,13.01)	2.06	(0.72,13.20) (0.66,6.37)	
Sex					NC
Male	inf	(0.26, inf)	inf	(0.29, inf)	
Female	2.46	(0.52,13.51)	1.90	(0.64,10.50) (0.60,6.01)	
Age					0.2790
>= 50 years	0.67	(0.04,25.94)	0.73	(0.08,19.66) (0.09,6.00)	
< 50 years	4.29	(0.81,32.49)	2.92	(0.86,31.61) (0.74,11.45)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.7 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	3	37.5				
No	11	2	18.2		21	5	23.8				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	9	40.9	(23.3, 61.3)	0.0514	32.6	(-2.5,57.4)
=4	6	2	33.3	(9.7, 70.0)	13	3	23.1	(8.2, 50.3)	0.8190	-10.3	(-58.0,32.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	10	35.7	(20.7, 54.2)	0.3944	15.7	(-15.0,41.1)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	3	20.0		29	10	34.5				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	3	20.0	(7.0, 45.2)	0.8258	7.5	(-32.7,39.5)
No	10	2	20.0	(5.7, 51.0)	20	9	45.0	(25.8, 65.8)	0.3035	25.0	(-14.9,55.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	3	18.8		34	12	35.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	11	34.4				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.7 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.1182
<4	7.62	(0.96,182.43)	4.91	(0.93,132.42) (0.70,34.25)	
=4	0.60	(0.06,6.88)	0.69	(0.13,6.66) (0.15,3.12)	
Baseline GPPGA score					NC
=3	2.22	(0.51,11.66)	1.79	(0.63,7.94) (0.58,5.51)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7877
Yes	1.75	(0.15,52.28)	1.60	(0.19,41.31) (0.20,12.99)	
No	3.27	(0.55,26.49)	2.25	(0.69,17.96) (0.59,8.52)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.7 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	10	38.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.7 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.8 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	15	42.9	(28.0, 59.1)	0.0829	26.2	(-3.8,48.6)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	5	35.7	(16.3, 61.2)	0.3501	35.7	(-35.2,66.5)
Female	15	3	20.0	(7.0, 45.2)	21	10	47.6	(28.3, 67.6)	0.1384	27.6	(-5.9,55.5)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	10	41.7	(24.5, 61.2)	0.0997	27.4	(-6.8,52.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	7	43.8	(23.1, 66.8)	0.3320	20.7	(-16.9,54.2)
White	5	0	0.0	(0.0, 43.4)	19	8	42.1	(23.1, 63.7)	0.1895	42.1	(-11.5,66.6)
Region											
Europe + Africa + US	5	0	0.0		21	9	42.9				
Asia(ex Japan) + Japan	13	3	23.1		14	6	42.9				
BMI											
< 25 kg/m2	9	1	11.1		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	2	16.7		24	9	37.5				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.8 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.75	(0.94,18.36)	2.57	(0.91,17.09) (0.85,7.74)	
Sex					NC
Male	inf	(0.37, inf)	inf	(0.40, inf)	
Female	3.64	(0.78,19.52)	2.38	(0.84,10.52) (0.79,7.20)	
Age					0.6837
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	4.29	(0.81,32.49)	2.92	(0.86,31.61) (0.74,11.45)	
Race					NC
Asian	2.59	(0.49,15.21)	1.90	(0.60,11.78) (0.61,5.91)	
White	inf	(0.98, inf)	inf	(0.77, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.8 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	6	75.0			
No	11	2	18.2		21	7	33.3			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8 (13.3,73.5)
=4	6	2	33.3	(9.7, 70.0)	13	2	15.4	(4.3, 42.2)	0.4859	-17.9 (-64.2,23.8)
Baseline GPPGA score										
=3	15	3	20.0	(7.0, 45.2)	28	14	50.0	(32.6, 67.4)	0.0874	30.0 (-2.1,55.3)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3 (-54.0,58.9)
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	3	20.0		29	14	48.3			
Background treatment prior to randomization										
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2 (-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	8	40.0	(21.9, 61.3)	0.3645	20.0 (-19.0,50.5)
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	3	18.8		34	14	41.2			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	3	16.7		32	14	43.8			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.8 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.0364
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	0.36	(0.03,4.76)	0.46	(0.03,6.63) (0.08,2.54)	
Baseline GPPGA score					NC
=3	4.00	(0.93,20.42)	2.50	(0.94,17.77) (0.85,7.35)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6012
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	2.67	(0.45,21.86)	2.00	(0.59,16.51) (0.52,7.72)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.8 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.8 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.9 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	15	42.9	(28.0, 59.1)	0.0235	31.7	(2.2,52.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	2	13.3	(3.7, 37.9)	21	8	38.1	(20.8, 59.1)	0.1384	24.8	(-6.9,51.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	4	36.4	(15.2, 64.6)	0.9287	11.4	(-47.2,55.4)
< 50 years	14	1	7.1	(1.3, 31.5)	24	11	45.8	(27.9, 64.9)	0.0221	38.7	(7.1,61.8)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	8	50.0	(28.0, 72.0)	0.0742	34.6	(-3.1,64.7)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	2	15.4		14	7	50.0				
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	9	37.5				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.9 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.00	(1.27,42.46)	3.86	(1.02,39.66) (0.99,15.05)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	4.00	(0.72,31.00)	2.86	(0.77,23.60) (0.70,11.59)	
Age					0.2799
>= 50 years	1.71	(0.13,55.79)	1.45	(0.26,37.76) (0.22,9.43)	
< 50 years	11.00	(1.46,255.71)	6.42	(1.08,177.30) (0.92,44.57)	
Race					NC
Asian	5.50	(0.91,44.05)	3.25	(0.95,26.73) (0.83,12.74)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.9 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	4	50.0				
No	11	1	9.1		21	8	38.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	12	54.5	(34.7, 73.1)	0.0148	46.2	(8.9,69.7)
=4	6	1	16.7	(3.0, 56.4)	13	3	23.1	(8.2, 50.3)	0.9119	6.4	(-41.0,42.7)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	13	46.4	(29.5, 64.2)	0.0504	33.1	(0.0,56.4)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	2	13.3		29	12	41.4				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	9	45.0	(25.8, 65.8)	0.3035	25.0	(-14.9,55.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	14	41.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	14	43.8				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.9 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.2773
<4	13.20	(1.67,308.36)	6.55	(1.18,185.27) (0.96,44.42)	
=4	1.50	(0.12,46.97)	1.38	(0.17,35.82) (0.18,10.71)	
Baseline GPPGA score					NC
=3	5.63	(1.12,41.24)	3.48	(1.00,37.27) (0.90,13.43)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	3.27	(0.55,26.49)	2.25	(0.69,17.96) (0.59,8.52)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.9 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.9 Proportion of patients with GPPASI 50 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.10 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	4	22.2	(9.0, 45.2)	35	6	17.1	(8.1, 32.7)	0.7741	-5.1	(-31.8,17.0)
Sex											
Male	3	0	0.0		14	2	14.3				
Female	15	4	26.7		21	4	19.0				
Age											
>= 50 years	4	1	25.0		11	0	0.0				
< 50 years	14	3	21.4		24	6	25.0				
Race											
Asian	13	4	30.8		16	3	18.8				
White	5	0	0.0		19	3	15.8				
Region											
Europe + Africa + US	5	0	0.0		21	3	14.3				
Asia(ex Japan) + Japan	13	4	30.8		14	3	21.4				
BMI											
< 25 kg/m2	9	2	22.2		15	3	20.0				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	1	20.0				
No	12	3	25.0		24	3	12.5				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.10 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.72	(0.17,3.36)	0.77	(0.24,2.99) (0.25,2.39)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.2.10 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	1	12.5			
No	11	3	27.3		21	3	14.3			
Baseline GPPGA pustulation subscore										
<4	12	2	16.7		22	3	13.6			
=4	6	2	33.3		13	3	23.1			
Baseline GPPGA score										
=3	15	4	26.7		28	5	17.9			
=4	3	0	0.0		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	1	33.3		6	1	16.7			
No	15	3	20.0		29	5	17.2			
Background treatment prior to randomization										
Yes	8	1	12.5		15	1	6.7			
No	10	3	30.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	4	25.0		34	6	17.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	4	22.2		32	6	18.8			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.10 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.10 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	4	25.0		26	5	19.2			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.10 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.11 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	17	48.6	(33.0, 64.4)	0.0382	31.9	(2.2,54.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	10	47.6	(28.3, 67.6)	0.1384	27.6	(-5.9,55.5)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	4	36.4	(15.2, 64.6)	0.9287	11.4	(-47.2,55.4)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	8	50.0	(28.0, 72.0)	0.1669	26.9	(-10.2,58.9)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	7	50.0	(26.8, 73.2)	0.1993	26.9	(-11.0,60.2)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	9	60.0	(35.7, 80.2)	0.0276	48.9	(3.6,76.6)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	3	30.0	(10.8, 60.3)	1.0000	-3.3	(-53.2,43.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	2	16.7		24	9	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.2.11 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.72	(1.18,22.95)	2.91	(1.02,17.10) (0.98,8.65)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	3.64	(0.78,19.52)	2.38	(0.84,10.52) (0.79,7.20)	
Age					0.4135
>= 50 years	1.71	(0.13,55.79)	1.45	(0.26,37.76) (0.22,9.43)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	3.33	(0.64,19.32)	2.17	(0.76,11.85) (0.72,6.55)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	3.33	(0.61,20.00)	2.17	(0.70,13.40) (0.71,6.66)	
BMI					NC
< 25 kg/m2	12.00	(1.27,295.27)	5.40	(1.12,151.26) (0.81,35.87)	
25 to < 30 kg/m2	0.86	(0.09,10.00)	0.90	(0.18,8.56) (0.21,3.94)	
>= 30 kg/m2	inf	(0.60, inf)	inf	(0.59, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.2.11 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	2	18.2	(5.1, 47.7)	21	8	38.1	(20.8, 59.1)	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	3	23.1	(8.2, 50.3)	0.8190	-10.3	(-58.0,32.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	16	57.1	(39.1, 73.5)	0.0250	37.1	(2.5,61.8)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	3	20.0		29	15	51.7				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	10	50.0	(29.9, 70.1)	0.1361	30.0	(-12.0,59.7)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	16	47.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	16	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.11 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.6221
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					0.0525
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	0.60	(0.06,6.88)	0.69	(0.13,6.66) (0.15,3.12)	
Baseline GPPGA score					NC
=3	5.33	(1.23,27.11)	2.86	(1.03,17.77) (0.99,8.26)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7348
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	4.00	(0.68,32.08)	2.50	(0.79,27.08) (0.67,9.31)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.11 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	13	50.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.11 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.12 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	14	40.0	(25.6, 56.4)	0.0476	28.9	(0.2,49.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	2	13.3	(3.7, 37.9)	21	8	38.1	(20.8, 59.1)	0.1384	24.8	(-6.9,51.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	3	27.3	(9.7, 56.6)	1.0000	2.3	(-55.5,46.5)
< 50 years	14	1	7.1	(1.3, 31.5)	24	11	45.8	(27.9, 64.9)	0.0221	38.7	(7.1,61.8)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	8	50.0	(28.0, 72.0)	0.0742	34.6	(-3.1,64.7)
White	5	0	0.0	(0.0, 43.4)	19	6	31.6	(15.4, 54.0)	0.2080	31.6	(-23.9,57.0)
Region											
Europe + Africa + US	5	0	0.0		21	7	33.3				
Asia(ex Japan) + Japan	13	2	15.4		14	7	50.0				
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	3	30.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	1	8.3		24	9	37.5				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.12 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.33	(1.13,37.92)	3.60	(1.00,39.66) (0.92,14.14)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	4.00	(0.72,31.00)	2.86	(0.77,23.60) (0.70,11.59)	
Age					0.2068
>= 50 years	1.13	(0.08,39.00)	1.09	(0.16,28.32) (0.15,7.69)	
< 50 years	11.00	(1.46,255.71)	6.42	(1.08,177.30) (0.92,44.57)	
Race					NC
Asian	5.50	(0.91,44.05)	3.25	(0.95,26.73) (0.83,12.74)	
White	inf	(0.62, inf)	inf	(0.54, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.12 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	3	37.5				
No	11	1	9.1		21	8	38.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	11	50.0	(30.7, 69.3)	0.0245	41.7	(6.6,65.7)
=4	6	1	16.7	(3.0, 56.4)	13	3	23.1	(8.2, 50.3)	0.9119	6.4	(-41.0,42.7)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	12	42.9	(26.5, 60.9)	0.0874	29.5	(-2.0,53.0)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	2	13.3		29	11	37.9				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	8	40.0	(21.9, 61.3)	0.3645	20.0	(-19.0,50.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	13	38.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	13	40.6				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.12 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.3060
<4	11.00	(1.40,258.77)	6.00	(1.10,167.09) (0.88,41.03)	
=4	1.50	(0.12,46.97)	1.38	(0.17,35.82) (0.18,10.71)	
Baseline GPPGA score					NC
=3	4.88	(0.96,35.90)	3.21	(0.94,29.05) (0.83,12.51)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	2.67	(0.45,21.86)	2.00	(0.59,16.51) (0.52,7.72)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.12 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.12 Proportion of patients with GPPASI 50 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.13 Proportion of patients with GPPASI 75 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	4	11.4	(4.5, 26.0)	0.7740	5.9	(-17.0,22.7)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	1	6.7		21	1	4.8				
Age											
>= 50 years	4	0	0.0		11	1	9.1				
< 50 years	14	1	7.1		24	3	12.5				
Race											
Asian	13	1	7.7		16	3	18.8				
White	5	0	0.0		19	1	5.3				
Region											
Europe + Africa + US	5	0	0.0		21	2	9.5				
Asia(ex Japan) + Japan	13	1	7.7		14	2	14.3				
BMI											
< 25 kg/m2	9	0	0.0		15	3	20.0				
25 to < 30 kg/m2	6	1	16.7		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	0	0.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	0	0.0				
No	12	1	8.3		24	2	8.3				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.13 Proportion of patients with GPPASI 75 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.13 Proportion of patients with GPPASI 75 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	1	12.5			
No	11	1	9.1		21	1	4.8			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	3	13.6			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	3	10.7			
=4	3	0	0.0		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	4	13.8			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	1	10.0		20	3	15.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	4	11.8			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	4	12.5			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.13 Proportion of patients with GPPASI 75 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.13 Proportion of patients with GPPASI 75 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	4	15.4			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.2.13 Proportion of patients with GPPASI 75 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.14 Proportion of patients with GPPASI 75 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	18	51.4	(35.6, 67.0)	0.0235	34.8	(4.3,56.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	11	52.4	(32.4, 71.7)	0.0586	32.4	(-1.2,59.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	12	50.0	(31.4, 68.6)	0.0344	35.7	(2.1,60.6)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	9	56.3	(33.2, 76.9)	0.0850	33.2	(-4.4,64.1)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	8	57.1	(32.6, 78.6)	0.0906	34.1	(-4.5,67.1)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	9	60.0	(35.7, 80.2)	0.0276	48.9	(3.6,76.6)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	3	30.0	(10.8, 60.3)	1.0000	-3.3	(-53.2,43.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	9	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.2.14 Proportion of patients with GPPASI 75 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.29	(1.33,25.66)	3.09	(1.06,17.10) (1.05,9.10)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	4.40	(0.94,23.48)	2.62	(0.97,11.76) (0.88,7.80)	
Age					0.6780
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	6.00	(1.13,44.82)	3.50	(1.02,31.61) (0.91,13.42)	
Race					NC
Asian	4.29	(0.82,24.72)	2.44	(0.91,11.85) (0.83,7.20)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	4.44	(0.80,26.56)	2.48	(0.88,13.48) (0.83,7.37)	
BMI					NC
< 25 kg/m2	12.00	(1.27,295.27)	5.40	(1.12,151.26) (0.81,35.87)	
25 to < 30 kg/m2	0.86	(0.09,10.00)	0.90	(0.18,8.56) (0.21,3.94)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.14 Proportion of patients with GPPASI 75 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	7	87.5				
No	11	2	18.2		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	4	30.8	(12.7, 57.6)	1.0000	-2.6	(-51.7,40.0)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	16	57.1	(39.1, 73.5)	0.0250	37.1	(2.5,61.8)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	15	51.7				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	11	55.0	(34.2, 74.2)	0.1143	35.0	(-5.4,65.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	17	53.1				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.14 Proportion of patients with GPPASI 75 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.0792
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	0.89	(0.11,9.49)	0.92	(0.23,6.67) (0.23,3.72)	
Baseline GPPGA score					NC
=3	5.33	(1.23,27.11)	2.86	(1.03,17.77) (0.99,8.26)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7956
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	4.89	(0.82,38.96)	2.75	(0.86,27.08) (0.75,10.11)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.14 Proportion of patients with GPPASI 75 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.14 Proportion of patients with GPPASI 75 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.15 Proportion of patients with GPPASI 75 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	15	42.9	(28.0, 59.1)	0.0235	31.7	(2.2,52.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	2	13.3	(3.7, 37.9)	21	9	42.9	(24.5, 63.5)	0.0727	29.5	(-2.6,56.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	4	36.4	(15.2, 64.6)	0.9287	11.4	(-47.2,55.4)
< 50 years	14	1	7.1	(1.3, 31.5)	24	11	45.8	(27.9, 64.9)	0.0221	38.7	(7.1,61.8)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	8	50.0	(28.0, 72.0)	0.0742	34.6	(-3.1,64.7)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	2	15.4		14	7	50.0				
BMI											
< 25 kg/m2	9	0	0.0		15	7	46.7				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	7	29.2				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.15 Proportion of patients with GPPASI 75 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.00	(1.27,42.46)	3.86	(1.02,39.66) (0.99,15.05)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	4.88	(0.89,37.29)	3.21	(0.92,27.20) (0.81,12.80)	
Age					0.2799
>= 50 years	1.71	(0.13,55.79)	1.45	(0.26,37.76) (0.22,9.43)	
< 50 years	11.00	(1.46,255.71)	6.42	(1.08,177.30) (0.92,44.57)	
Race					NC
Asian	5.50	(0.91,44.05)	3.25	(0.95,26.73) (0.83,12.74)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.15 Proportion of patients with GPPASI 75 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		21	6	28.6				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	11	50.0	(30.7, 69.3)	0.0245	41.7	(6.6,65.7)
=4	6	1	16.7	(3.0, 56.4)	13	4	30.8	(12.7, 57.6)	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	13	46.4	(29.5, 64.2)	0.0504	33.1	(0.0,56.4)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	11	37.9				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	5	33.3	(15.2, 58.3)	0.1229	33.3	(-6.9,61.6)
No	10	2	20.0	(5.7, 51.0)	20	10	50.0	(29.9, 70.1)	0.1361	30.0	(-12.0,59.7)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		34	15	44.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	14	43.8				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.15 Proportion of patients with GPPASI 75 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4009
<4	11.00	(1.40,258.77)	6.00	(1.10,167.09) (0.88,41.03)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					NC
=3	5.63	(1.12,41.24)	3.48	(1.00,37.27) (0.90,13.43)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.07, inf)	inf	(0.81, inf)	
No	4.00	(0.68,32.08)	2.50	(0.79,27.08) (0.67,9.31)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.2.15 Proportion of patients with GPPASI 75 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	12	46.2			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.2.15 Proportion of patients with GPPASI 75 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.16 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	22	62.9	(46.3, 76.8)	0.0005	51.7	(21.5,70.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	14	66.7	(45.4, 82.8)	0.0021	53.3	(20.9,76.3)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	16	66.7	(46.7, 82.0)	0.0005	59.5	(23.0,79.5)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	11	57.9	(36.3, 76.9)	0.0394	57.9	(1.8,79.8)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	12	57.1	(36.5, 75.5)	0.0329	57.1	(3.1,79.0)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0	(0.0, 29.9)	15	10	66.7	(41.7, 84.8)	0.0016	66.7	(28.5,88.2)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	6	60.0	(31.3, 83.2)	0.4303	26.7	(-26.3,69.1)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	13	54.2				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.16 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	13.54	(2.82,94.24)	5.66	(1.69,65.20) (1.49,21.42)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	13.00	(2.29,97.10)	5.00	(1.48,55.17) (1.33,18.81)	
Age					0.2753
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	26.00	(3.31,588.27)	9.33	(1.94,278.26) (1.38,63.01)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.82, inf)	inf	(1.02, inf)	
Region					NC
Europe + Africa + US	inf	(1.81, inf)	inf	(0.98, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					NC
< 25 kg/m2	inf	(4.67, inf)	inf	(1.67, inf)	
25 to < 30 kg/m2	3.00	(0.33,31.20)	1.80	(0.55,19.53) (0.52,6.22)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.16 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	1	9.1	(1.6, 37.7)	21	11	52.4	(32.4, 71.7)	0.0222	43.3	(3.8,69.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	15	68.2	(47.3, 83.6)	0.0010	59.8	(21.1,80.7)
=4	6	1	16.7	(3.0, 56.4)	13	7	53.8	(29.1, 76.8)	0.1750	37.2	(-16.0,71.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	19	67.9	(49.3, 82.1)	0.0014	54.5	(20.9,75.5)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	18	62.1				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	2	20.0	(5.7, 51.0)	20	15	75.0	(53.1, 88.8)	0.0088	55.0	(11.5,81.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	21	61.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	20	62.5				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.16 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9448
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	11.00	(1.36,260.77)	5.76	(1.10,161.22) (0.85,39.02)	
Baseline GPPGA pustulation subscore					0.4930
<4	23.57	(2.85,541.70)	8.18	(1.75,243.60) (1.23,54.60)	
=4	5.83	(0.54,157.00)	3.23	(0.70,87.84) (0.50,20.73)	
Baseline GPPGA score					NC
=3	13.72	(2.61,99.10)	5.09	(1.62,54.40) (1.37,18.96)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	12.00	(1.84,96.20)	3.75	(1.14,38.64) (1.06,13.29)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.16 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	18	69.2			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.16 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.17 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	21	60.0	(43.6, 74.4)	0.0052	43.3	(9.6,64.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	3	20.0	(7.0, 45.2)	21	13	61.9	(40.9, 79.2)	0.0200	41.9	(8.1,67.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	15	62.5	(42.7, 78.8)	0.0069	48.2	(12.2,71.4)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	11	68.8	(44.4, 85.8)	0.0181	45.7	(7.4,74.3)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	10	71.4	(45.4, 88.3)	0.0154	48.4	(8.7,77.3)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	12	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.17 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.50	(1.86,36.24)	3.60	(1.27,27.91) (1.24,10.47)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	6.50	(1.37,34.65)	3.10	(1.12,22.60) (1.07,8.99)	
Age					0.5385
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	10.00	(1.85,73.97)	4.38	(1.21,45.03) (1.17,16.38)	
Race					NC
Asian	7.33	(1.33,43.09)	2.98	(1.14,12.38) (1.05,8.48)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	8.33	(1.40,51.74)	3.10	(1.21,13.49) (1.09,8.81)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.17 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	10	47.6	(28.3, 67.6)	0.1280	29.4	(-8.2,58.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	7	53.8	(29.1, 76.8)	0.4869	20.5	(-30.9,61.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	18	64.3	(45.8, 79.3)	0.0071	44.3	(7.0,68.0)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		29	17	58.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	19	59.4				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.17 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5439
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	4.09	(0.72,32.21)	2.62	(0.79,28.37) (0.69,9.92)	
Baseline GPPGA pustulation subscore					0.1799
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	2.33	(0.29,22.83)	1.62	(0.53,15.12) (0.47,5.57)	
Baseline GPPGA score					NC
=3	7.20	(1.63,36.65)	3.21	(1.13,17.77) (1.13,9.18)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9561
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.2.17 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.17 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.18 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	18	51.4	(35.6, 67.0)	0.0067	40.3	(9.6,60.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	10	47.6	(28.3, 67.6)	0.0417	34.3	(2.6,60.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	10	62.5	(38.6, 81.5)	0.0115	47.1	(10.7,74.8)
White	5	0	0.0	(0.0, 43.4)	19	8	42.1	(23.1, 63.7)	0.1895	42.1	(-11.5,66.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	9	42.9	(24.5, 63.5)	0.1718	42.9	(-9.2,67.1)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	9	64.3	(38.8, 83.7)	0.0112	48.9	(9.3,77.9)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	10	41.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.18 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.47	(1.80,59.33)	4.63	(1.21,52.13) (1.21,17.78)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	5.91	(1.09,44.76)	3.57	(1.06,38.68) (0.91,14.00)	
Age					0.2902
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	9.17	(1.47,72.54)	4.06	(1.23,43.94) (1.07,15.36)	
White	inf	(0.98, inf)	inf	(0.77, inf)	
Region					NC
Europe + Africa + US	inf	(1.04, inf)	inf	(0.76, inf)	
Asia(ex Japan) + Japan	9.90	(1.50,80.39)	4.18	(1.22,30.59) (1.10,15.85)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.18 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	1	16.7	(3.0, 56.4)	13	5	38.5	(17.7, 64.5)	0.4859	21.8	(-28.2,58.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	16	57.1	(39.1, 73.5)	0.0070	43.8	(7.0,66.5)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	14	48.3				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	12	60.0	(38.7, 78.1)	0.0751	40.0	(-1.9,68.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	16	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.18 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.8675
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.4160
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	3.13	(0.29,88.28)	2.31	(0.45,60.18) (0.34,15.69)	
Baseline GPPGA score					NC
=3	8.67	(1.70,62.73)	4.29	(1.13,41.33) (1.13,16.20)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	6.00	(1.00,47.64)	3.00	(0.94,27.08) (0.83,10.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.18 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.18 Proportion of patients with GPPASI 75 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.19 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	1	2.9	(0.5, 14.5)	0.7741	-2.7 (-24.4,11.7)
Sex										
Male	3	0	0.0		14	0	0.0			
Female	15	1	6.7		21	1	4.8			
Age										
>= 50 years	4	0	0.0		11	1	9.1			
< 50 years	14	1	7.1		24	0	0.0			
Race										
Asian	13	1	7.7		16	1	6.3			
White	5	0	0.0		19	0	0.0			
Region										
Europe + Africa + US	5	0	0.0		21	0	0.0			
Asia(ex Japan) + Japan	13	1	7.7		14	1	7.1			
BMI										
< 25 kg/m2	9	0	0.0		15	1	6.7			
25 to < 30 kg/m2	6	1	16.7		10	0	0.0			
>= 30 kg/m2	3	0	0.0		10	0	0.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	1	8.3		24	1	4.2			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.19 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.19 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	1	12.5			
No	11	1	9.1		21	0	0.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	0	0.0			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	0	0.0			
=4	3	0	0.0		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	1	3.4			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	1	5.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	1	2.9			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	1	3.1			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.19 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.19 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	1	3.8			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.19 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.20 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	8	22.9	(12.1, 39.0)	0.1336	17.3 (-7.8,36.0)
Sex										
Male	3	0	0.0		14	3	21.4			
Female	15	1	6.7		21	5	23.8			
Age										
>= 50 years	4	0	0.0		11	2	18.2			
< 50 years	14	1	7.1		24	6	25.0			
Race										
Asian	13	1	7.7		16	4	25.0			
White	5	0	0.0		19	4	21.1			
Region										
Europe + Africa + US	5	0	0.0		21	4	19.0			
Asia(ex Japan) + Japan	13	1	7.7		14	4	28.6			
BMI										
< 25 kg/m2	9	0	0.0		15	4	26.7			
25 to < 30 kg/m2	6	1	16.7		10	2	20.0			
>= 30 kg/m2	3	0	0.0		10	2	20.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	1	20.0			
No	12	1	8.3		24	6	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.20 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.04	(0.70,118.83)	4.11	(0.72,107.24) (0.56,30.39)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.20 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	2	25.0			
No	11	1	9.1		21	5	23.8			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	6	27.3			
=4	6	1	16.7		13	2	15.4			
Baseline GPPGA score										
=3	15	1	6.7		28	7	25.0			
=4	3	0	0.0		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	7	24.1			
Background treatment prior to randomization										
Yes	8	0	0.0		15	2	13.3			
No	10	1	10.0		20	6	30.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	1	6.3		34	7	20.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	8	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.20 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.20 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	6	23.1			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.20 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.21 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	11	31.4	(18.6, 48.0)	0.1331	20.3	(-7.8,41.4)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	2	13.3		21	7	33.3				
Age											
>= 50 years	4	1	25.0		11	3	27.3				
< 50 years	14	1	7.1		24	8	33.3				
Race											
Asian	13	2	15.4		16	5	31.3				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	7	33.3				
Asia(ex Japan) + Japan	13	2	15.4		14	4	28.6				
BMI											
< 25 kg/m2	9	0	0.0		15	6	40.0				
25 to < 30 kg/m2	6	2	33.3		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	6	25.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.21 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.67	(0.76,26.61)	2.83	(0.79,27.91) (0.70,11.42)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.21 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	4	50.0				
No	11	1	9.1		21	5	23.8				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	9	40.9	(23.3, 61.3)	0.0514	32.6	(-2.5,57.4)
=4	6	1	16.7	(3.0, 56.4)	13	2	15.4	(4.3, 42.2)	1.0000	-1.3	(-47.5,34.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	10	35.7	(20.7, 54.2)	0.1417	22.4	(-9.8,46.0)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	1	16.7				
No	15	2	13.3		29	10	34.5				
Background treatment prior to randomization											
Yes	8	0	0.0		15	5	33.3				
No	10	2	20.0		20	6	30.0				
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		34	11	32.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	10	31.3				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.21 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.2640
<4	7.62	(0.96,182.43)	4.91	(0.93,132.42) (0.70,34.25)	
=4	0.91	(0.06,31.93)	0.92	(0.09,24.95) (0.10,8.31)	
Baseline GPPGA score					NC
=3	3.61	(0.71,27.04)	2.68	(0.77,29.05) (0.67,10.67)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.21 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	8	30.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.21 Proportion of patients with GPPASI 75 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.22 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	0	0.0	(0.0, 9.9)	0.3093	-5.6 (-27.3,5.5)
Sex										
Male	3	0	0.0		14	0	0.0			
Female	15	1	6.7		21	0	0.0			
Age										
>= 50 years	4	0	0.0		11	0	0.0			
< 50 years	14	1	7.1		24	0	0.0			
Race										
Asian	13	1	7.7		16	0	0.0			
White	5	0	0.0		19	0	0.0			
Region										
Europe + Africa + US	5	0	0.0		21	0	0.0			
Asia(ex Japan) + Japan	13	1	7.7		14	0	0.0			
BMI										
< 25 kg/m2	9	0	0.0		15	0	0.0			
25 to < 30 kg/m2	6	1	16.7		10	0	0.0			
>= 30 kg/m2	3	0	0.0		10	0	0.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	1	8.3		24	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.22 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.22 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	1	9.1		21	0	0.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	0	0.0			
=4	6	1	16.7		13	0	0.0			
Baseline GPPGA score										
=3	15	1	6.7		28	0	0.0			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	0	0.0			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	0	0.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	0	0.0			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.22 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.22 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	0	0.0			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.22 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.23 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	9	25.7	(14.2, 42.1)	0.5038	9.0	(-18.0,30.7)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	3	20.0		21	5	23.8				
Age											
>= 50 years	4	1	25.0		11	4	36.4				
< 50 years	14	2	14.3		24	5	20.8				
Race											
Asian	13	3	23.1		16	3	18.8				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	6	28.6				
Asia(ex Japan) + Japan	13	3	23.1		14	3	21.4				
BMI											
< 25 kg/m2	9	1	11.1		15	5	33.3				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	2	16.7		24	5	20.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.23 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.73	(0.41,8.92)	1.54	(0.50,7.64) (0.48,5.00)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.23 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	3	37.5			
No	11	2	18.2		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	8	36.4			
=4	6	2	33.3		13	1	7.7			
Baseline GPPGA score										
=3	15	3	20.0	(7.0, 45.2)	28	9	32.1	(17.9, 50.7)	0.4499	12.1 (-19.2,37.5)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	3	20.0		29	8	27.6			
Background treatment prior to randomization										
Yes	8	1	12.5		15	3	20.0			
No	10	2	20.0		20	6	30.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	3	18.8		34	8	23.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	3	16.7		32	8	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.23 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	1.89	(0.43,10.07)	1.61	(0.54,7.92) (0.51,5.06)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.23 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	6	23.1			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.23 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.24 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	10	28.6	(16.3, 45.1)	0.1771	17.5 (-8.8,37.8)
Sex										
Male	3	0	0.0		14	3	21.4			
Female	15	2	13.3		21	7	33.3			
Age										
>= 50 years	4	1	25.0		11	2	18.2			
< 50 years	14	1	7.1		24	8	33.3			
Race										
Asian	13	2	15.4		16	6	37.5			
White	5	0	0.0		19	4	21.1			
Region										
Europe + Africa + US	5	0	0.0		21	5	23.8			
Asia(ex Japan) + Japan	13	2	15.4		14	5	35.7			
BMI										
< 25 kg/m2	9	0	0.0		15	5	33.3			
25 to < 30 kg/m2	6	2	33.3		10	2	20.0			
>= 30 kg/m2	3	0	0.0		10	3	30.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	1	20.0			
No	12	1	8.3		24	7	29.2			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.24 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.20	(0.66,23.45)	2.57	(0.72,27.91) (0.63,10.51)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.24 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	2	25.0				
No	11	1	9.1		21	6	28.6				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3		22	8	36.4				
=4	6	1	16.7		13	2	15.4				
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	9	32.1	(17.9, 50.7)	0.3199	18.8	(-10.7,42.5)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	2	13.3		29	8	27.6				
Background treatment prior to randomization											
Yes	8	0	0.0		15	5	33.3				
No	10	2	20.0		20	5	25.0				
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		34	10	29.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	9	28.1				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.24 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	3.08	(0.59,23.32)	2.41	(0.69,22.04) (0.60,9.76)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.24 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	8	30.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.24 Proportion of patients with GPPASI 75 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.25 Proportion of patients with GPPASI 90 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	0	0.0	(0.0, 9.9)	0.3093	-5.6 (-27.3,5.5)
Sex										
Male	3	0	0.0		14	0	0.0			
Female	15	1	6.7		21	0	0.0			
Age										
>= 50 years	4	0	0.0		11	0	0.0			
< 50 years	14	1	7.1		24	0	0.0			
Race										
Asian	13	1	7.7		16	0	0.0			
White	5	0	0.0		19	0	0.0			
Region										
Europe + Africa + US	5	0	0.0		21	0	0.0			
Asia(ex Japan) + Japan	13	1	7.7		14	0	0.0			
BMI										
< 25 kg/m2	9	0	0.0		15	0	0.0			
25 to < 30 kg/m2	6	1	16.7		10	0	0.0			
>= 30 kg/m2	3	0	0.0		10	0	0.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	1	8.3		24	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.25 Proportion of patients with GPPASI 90 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.25 Proportion of patients with GPPASI 90 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	1	9.1		21	0	0.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	0	0.0			
=4	6	1	16.7		13	0	0.0			
Baseline GPPGA score										
=3	15	1	6.7		28	0	0.0			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	0	0.0			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	0	0.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	0	0.0			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.25 Proportion of patients with GPPASI 90 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.25 Proportion of patients with GPPASI 90 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	0	0.0			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.25 Proportion of patients with GPPASI 90 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.26 Proportion of patients with GPPASI 90 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	9	25.7	(14.2, 42.1)	0.3121	14.6	(-11.7,34.8)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	2	13.3		21	5	23.8				
Age											
>= 50 years	4	1	25.0		11	2	18.2				
< 50 years	14	1	7.1		24	7	29.2				
Race											
Asian	13	2	15.4		16	3	18.8				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	6	28.6				
Asia(ex Japan) + Japan	13	2	15.4		14	3	21.4				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	3	30.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	5	20.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.26 Proportion of patients with GPPASI 90 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.77	(0.56,20.53)	2.31	(0.61,22.59) (0.56,9.60)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.26 Proportion of patients with GPPASI 90 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	3	37.5			
No	11	1	9.1		21	5	23.8			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	8	36.4			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	9	32.1	(17.9, 50.7)	0.3199	18.8 (-10.7,42.5)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	8	27.6			
Background treatment prior to randomization										
Yes	8	0	0.0		15	2	13.3			
No	10	2	20.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	2	12.5		34	8	23.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	9	28.1			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.26 Proportion of patients with GPPASI 90 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	3.08	(0.59,23.32)	2.41	(0.69,22.04) (0.60,9.76)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.26 Proportion of patients with GPPASI 90 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	6	23.1			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.26 Proportion of patients with GPPASI 90 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.27 Proportion of patients with GPPASI 90 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	11	31.4	(18.6, 48.0)	0.1331	20.3	(-7.8,41.4)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	2	13.3		21	7	33.3				
Age											
>= 50 years	4	1	25.0		11	3	27.3				
< 50 years	14	1	7.1		24	8	33.3				
Race											
Asian	13	2	15.4		16	6	37.5				
White	5	0	0.0		19	5	26.3				
Region											
Europe + Africa + US	5	0	0.0		21	6	28.6				
Asia(ex Japan) + Japan	13	2	15.4		14	5	35.7				
BMI											
< 25 kg/m2	9	0	0.0		15	5	33.3				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	1	8.3		24	7	29.2				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.27 Proportion of patients with GPPASI 90 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.67	(0.76,26.61)	2.83	(0.79,27.91) (0.70,11.42)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.27 Proportion of patients with GPPASI 90 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	3	37.5				
No	11	1	9.1		21	6	28.6				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	9	40.9	(23.3, 61.3)	0.0514	32.6	(-2.5,57.4)
=4	6	1	16.7	(3.0, 56.4)	13	2	15.4	(4.3, 42.2)	1.0000	-1.3	(-47.5,34.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	10	35.7	(20.7, 54.2)	0.1417	22.4	(-9.8,46.0)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	2	13.3		29	9	31.0				
Background treatment prior to randomization											
Yes	8	0	0.0		15	5	33.3				
No	10	2	20.0		20	6	30.0				
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		34	11	32.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	10	31.3				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.27 Proportion of patients with GPPASI 90 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.2640
<4	7.62	(0.96,182.43)	4.91	(0.93,132.42) (0.70,34.25)	
=4	0.91	(0.06,31.93)	0.92	(0.09,24.95) (0.10,8.31)	
Baseline GPPGA score					NC
=3	3.61	(0.71,27.04)	2.68	(0.77,29.05) (0.67,10.67)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.27 Proportion of patients with GPPASI 90 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	8	30.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.27 Proportion of patients with GPPASI 90 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.2.28 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	21	60.0	(43.6, 74.4)	0.0015	48.9	(17.3,69.2)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	13	61.9	(40.9, 79.2)	0.0040	48.6	(15.4,73.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	15	62.5	(42.7, 78.8)	0.0012	55.4	(17.5,76.9)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	10	62.5	(38.6, 81.5)	0.0115	47.1	(10.7,74.8)
White	5	0	0.0	(0.0, 43.4)	19	11	57.9	(36.3, 76.9)	0.0394	57.9	(1.8,79.8)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	12	57.1	(36.5, 75.5)	0.0329	57.1	(3.1,79.0)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	9	64.3	(38.8, 83.7)	0.0112	48.9	(9.3,77.9)
BMI											
< 25 kg/m2	9	0	0.0	(0.0, 29.9)	15	10	66.7	(41.7, 84.8)	0.0016	66.7	(28.5,88.2)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	6	60.0	(31.3, 83.2)	0.4303	26.7	(-26.3,69.1)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	12	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.28 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	12.00	(2.52,83.59)	5.40	(1.56,65.20) (1.42,20.51)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	10.56	(1.90,78.88)	4.64	(1.27,45.17) (1.22,17.61)	
Age					0.2978
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	21.67	(2.80,492.31)	8.75	(1.72,256.83) (1.29,59.32)	
Race					NC
Asian	9.17	(1.47,72.54)	4.06	(1.23,43.94) (1.07,15.36)	
White	inf	(1.82, inf)	inf	(1.02, inf)	
Region					NC
Europe + Africa + US	inf	(1.81, inf)	inf	(0.98, inf)	
Asia(ex Japan) + Japan	9.90	(1.50,80.39)	4.18	(1.22,30.59) (1.10,15.85)	
BMI					NC
< 25 kg/m2	inf	(4.67, inf)	inf	(1.67, inf)	
25 to < 30 kg/m2	3.00	(0.33,31.20)	1.80	(0.55,19.53) (0.52,6.22)	
>= 30 kg/m2	inf	(0.60, inf)	inf	(0.59, inf)	
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.28 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	1	9.1	(1.6, 37.7)	21	10	47.6	(28.3, 67.6)	0.0412	38.5	(1.1,64.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	1	16.7	(3.0, 56.4)	13	7	53.8	(29.1, 76.8)	0.1750	37.2	(-16.0,71.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	18	64.3	(45.8, 79.3)	0.0019	51.0	(16.3,73.4)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	17	58.6				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	15	75.0	(53.1, 88.8)	0.0088	55.0	(11.5,81.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	19	59.4				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.28 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9987
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	9.09	(1.13,217.30)	5.24	(1.01,144.12) (0.77,35.79)	
Baseline GPPGA pustulation subscore					0.5262
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	5.83	(0.54,157.00)	3.23	(0.70,87.84) (0.50,20.73)	
Baseline GPPGA score					NC
=3	11.70	(2.26,84.47)	4.82	(1.48,54.41) (1.29,18.04)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	12.00	(1.84,96.20)	3.75	(1.14,38.64) (1.06,13.29)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.28 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.28 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.29 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	20	57.1	(40.9, 72.0)	0.0018	46.0	(13.3,66.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	12	57.1	(36.5, 75.5)	0.0079	43.8	(10.2,68.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	14	58.3	(38.8, 75.5)	0.0025	51.2	(17.5,72.7)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0	(0.0, 29.9)	15	10	66.7	(41.7, 84.8)	0.0016	66.7	(28.5,88.2)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	12	50.0				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.29 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	10.67	(2.25,74.40)	5.14	(1.44,52.13) (1.35,19.60)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	8.67	(1.58,64.88)	4.29	(1.19,38.68) (1.12,16.41)	
Age					0.3231
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	18.20	(2.38,415.48)	8.17	(1.54,236.07) (1.20,55.63)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					NC
< 25 kg/m2	inf	(4.67, inf)	inf	(1.67, inf)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.60, inf)	inf	(0.59, inf)	
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.2.29 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	1	9.1	(1.6, 37.7)	21	10	47.6	(28.3, 67.6)	0.0412	38.5	(1.1,64.1)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	1	16.7	(3.0, 56.4)	13	7	53.8	(29.1, 76.8)	0.1750	37.2	(-16.0,71.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	17	60.7	(42.4, 76.4)	0.0051	47.4	(11.6,69.6)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	19	55.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.29 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9108
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	9.09	(1.13,217.30)	5.24	(1.01,144.12) (0.77,35.79)	
Baseline GPPGA pustulation subscore					0.5630
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	5.83	(0.54,157.00)	3.23	(0.70,87.84) (0.50,20.73)	
Baseline GPPGA score					NC
=3	10.05	(1.96,72.58)	4.55	(1.27,54.41) (1.21,17.12)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.29 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	16	61.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.2.29 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.2.30 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	18	51.4	(35.6, 67.0)	0.0067	40.3	(9.6,60.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	10	47.6	(28.3, 67.6)	0.0417	34.3	(2.6,60.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	10	62.5	(38.6, 81.5)	0.0115	47.1	(10.7,74.8)
White	5	0	0.0	(0.0, 43.4)	19	8	42.1	(23.1, 63.7)	0.1895	42.1	(-11.5,66.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	9	42.9	(24.5, 63.5)	0.1718	42.9	(-9.2,67.1)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	9	64.3	(38.8, 83.7)	0.0112	48.9	(9.3,77.9)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	10	41.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.30 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.47	(1.80,59.33)	4.63	(1.21,52.13) (1.21,17.78)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	5.91	(1.09,44.76)	3.57	(1.06,38.68) (0.91,14.00)	
Age					0.2902
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	9.17	(1.47,72.54)	4.06	(1.23,43.94) (1.07,15.36)	
White	inf	(0.98, inf)	inf	(0.77, inf)	
Region					NC
Europe + Africa + US	inf	(1.04, inf)	inf	(0.76, inf)	
Asia(ex Japan) + Japan	9.90	(1.50,80.39)	4.18	(1.22,30.59) (1.10,15.85)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.2.30 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	1	16.7	(3.0, 56.4)	13	5	38.5	(17.7, 64.5)	0.4859	21.8	(-28.2,58.2)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	16	57.1	(39.1, 73.5)	0.0070	43.8	(7.0,66.5)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	14	48.3				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	12	60.0	(38.7, 78.1)	0.0751	40.0	(-1.9,68.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	16	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.2.30 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.8675
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.4160
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	3.13	(0.29,88.28)	2.31	(0.45,60.18) (0.34,15.69)	
Baseline GPPGA score					NC
=3	8.67	(1.70,62.73)	4.29	(1.13,41.33) (1.13,16.20)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	6.00	(1.00,47.64)	3.00	(0.94,27.08) (0.83,10.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.2.30 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.30 Proportion of patients with GPPASI 90 pustulation subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.31 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	0	0.0	(0.0, 9.9)	0.3093	-5.6 (-27.3,5.5)
Sex										
Male	3	0	0.0		14	0	0.0			
Female	15	1	6.7		21	0	0.0			
Age										
>= 50 years	4	0	0.0		11	0	0.0			
< 50 years	14	1	7.1		24	0	0.0			
Race										
Asian	13	1	7.7		16	0	0.0			
White	5	0	0.0		19	0	0.0			
Region										
Europe + Africa + US	5	0	0.0		21	0	0.0			
Asia(ex Japan) + Japan	13	1	7.7		14	0	0.0			
BMI										
< 25 kg/m2	9	0	0.0		15	0	0.0			
25 to < 30 kg/m2	6	1	16.7		10	0	0.0			
>= 30 kg/m2	3	0	0.0		10	0	0.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	1	8.3		24	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.31 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.31 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	1	9.1		21	0	0.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	0	0.0			
=4	6	1	16.7		13	0	0.0			
Baseline GPPGA score										
=3	15	1	6.7		28	0	0.0			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	0	0.0			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	0	0.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	0	0.0			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.31 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.31 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	0	0.0			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.31 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.32 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	5	14.3	(6.3, 29.4)	0.4577	8.7	(-14.4,25.9)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	1	6.7		21	2	9.5				
Age											
>= 50 years	4	0	0.0		11	1	9.1				
< 50 years	14	1	7.1		24	4	16.7				
Race											
Asian	13	1	7.7		16	2	12.5				
White	5	0	0.0		19	3	15.8				
Region											
Europe + Africa + US	5	0	0.0		21	3	14.3				
Asia(ex Japan) + Japan	13	1	7.7		14	2	14.3				
BMI											
< 25 kg/m2	9	0	0.0		15	3	20.0				
25 to < 30 kg/m2	6	1	16.7		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	1	20.0				
No	12	1	8.3		24	3	12.5				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.32 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.83	(0.35,71.13)	2.57	(0.41,65.20) (0.32,20.39)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.32 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	1	12.5			
No	11	1	9.1		21	3	14.3			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	4	18.2			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	5	17.9			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	5	17.2			
Background treatment prior to randomization										
Yes	8	0	0.0		15	2	13.3			
No	10	1	10.0		20	3	15.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	1	6.3		34	4	11.8			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	5	15.6			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.32 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.32 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	3	11.5			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.32 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.33 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	Risk diff. (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	6	17.1	(8.1, 32.7)	0.7741	6.0	(-19.1,25.6)
Sex											
Male	3	0	0.0		14	2	14.3				
Female	15	2	13.3		21	4	19.0				
Age											
>= 50 years	4	1	25.0		11	2	18.2				
< 50 years	14	1	7.1		24	4	16.7				
Race											
Asian	13	2	15.4		16	2	12.5				
White	5	0	0.0		19	4	21.1				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	2	15.4		14	1	7.1				
BMI											
< 25 kg/m2	9	0	0.0		15	5	33.3				
25 to < 30 kg/m2	6	2	33.3		10	0	0.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	1	20.0				
No	12	1	8.3		24	3	12.5				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.33 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.66	(0.31,13.00)	1.54	(0.36,17.09) (0.35,6.89)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.33 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	2	25.0			
No	11	1	9.1		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	5	22.7			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	2	13.3		28	6	21.4			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	2	13.3		29	6	20.7			
Background treatment prior to randomization										
Yes	8	0	0.0		15	3	20.0			
No	10	2	20.0		20	3	15.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	2	12.5		34	6	17.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	5	15.6			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.33 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.33 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	5	19.2			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.33 Proportion of patients with GPPASI 90 erythema subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.34 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	0	0.0		35	0	0.0			
Sex										
Male	3	0	0.0		14	0	0.0			
Female	15	0	0.0		21	0	0.0			
Age										
>= 50 years	4	0	0.0		11	0	0.0			
< 50 years	14	0	0.0		24	0	0.0			
Race										
Asian	13	0	0.0		16	0	0.0			
White	5	0	0.0		19	0	0.0			
Region										
Europe + Africa + US	5	0	0.0		21	0	0.0			
Asia(ex Japan) + Japan	13	0	0.0		14	0	0.0			
BMI										
< 25 kg/m2	9	0	0.0		15	0	0.0			
25 to < 30 kg/m2	6	0	0.0		10	0	0.0			
>= 30 kg/m2	3	0	0.0		10	0	0.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	0	0.0		24	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.34 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall					
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.34 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	0	0.0		21	0	0.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	0	0.0			
=4	6	0	0.0		13	0	0.0			
Baseline GPPGA score										
=3	15	0	0.0		28	0	0.0			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	0	0.0		29	0	0.0			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	0	0.0		20	0	0.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	0	0.0		34	0	0.0			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	0	0.0		32	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.34 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.34 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	0	0.0		26	0	0.0			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.34 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.35 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	8	22.9	(12.1, 39.0)	0.1336	17.3	(-7.8,36.0)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	1	6.7		21	4	19.0				
Age											
>= 50 years	4	0	0.0		11	3	27.3				
< 50 years	14	1	7.1		24	5	20.8				
Race											
Asian	13	1	7.7		16	3	18.8				
White	5	0	0.0		19	5	26.3				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	1	7.7		14	3	21.4				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	1	16.7		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	1	8.3		24	5	20.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.35 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.04	(0.70,118.83)	4.11	(0.72,107.24) (0.56,30.39)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.35 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	3	37.5			
No	11	1	9.1		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	7	31.8			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	8	28.6			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	7	24.1			
Background treatment prior to randomization										
Yes	8	0	0.0		15	2	13.3			
No	10	1	10.0		20	6	30.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	1	6.3		34	7	20.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	8	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.35 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.35 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	6	23.1			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.35 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.36 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	8	22.9	(12.1, 39.0)	0.3797	11.7	(-13.7,31.8)
Sex											
Male	3	0	0.0		14	2	14.3				
Female	15	2	13.3		21	6	28.6				
Age											
>= 50 years	4	1	25.0		11	2	18.2				
< 50 years	14	1	7.1		24	6	25.0				
Race											
Asian	13	2	15.4		16	4	25.0				
White	5	0	0.0		19	4	21.1				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	2	15.4		14	3	21.4				
BMI											
< 25 kg/m2	9	0	0.0		15	5	33.3				
25 to < 30 kg/m2	6	2	33.3		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	1	20.0				
No	12	1	8.3		24	5	20.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.36 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.37	(0.47,17.83)	2.06	(0.54,17.10) (0.49,8.70)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.36 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	2	25.0			
No	11	1	9.1		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	7	31.8			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	8	28.6	(15.3, 47.1)	0.3944	15.2 (-14.6,38.7)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	7	24.1			
Background treatment prior to randomization										
Yes	8	0	0.0		15	4	26.7			
No	10	2	20.0		20	4	20.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	2	12.5		34	8	23.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	7	21.9			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.36 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	2.60	(0.49,19.97)	2.14	(0.59,17.77) (0.52,8.84)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.36 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	6	23.1			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.2.36 Proportion of patients with GPPASI 90 scaling subscore overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.3 Analysis of patient reported outcome

1.2.3.1 Pain VAS score

Table 2.3.1.1 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 1 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	16	6	37.5	(18.5, 61.4)	34	16	47.1	(31.5, 63.3)	0.7988	9.6	(-21.4,37.3)
Sex											
Male	3	1	33.3	(6.1, 79.2)	13	7	53.8	(29.1, 76.8)	0.7901	20.5	(-42.4,67.0)
Female	13	5	38.5	(17.7, 64.5)	21	9	42.9	(24.5, 63.5)	0.8686	4.4	(-31.4,37.1)
Age											
>= 50 years	2	0	0.0	(0.0, 65.8)	10	6	60.0	(31.3, 83.2)	0.2096	60.0	(-26.4,87.8)
< 50 years	14	6	42.9	(21.4, 67.4)	24	10	41.7	(24.5, 61.2)	1.0000	-1.2	(-34.0,31.0)
Race											
Asian	11	4	36.4	(15.2, 64.6)	15	4	26.7	(10.9, 52.0)	0.6599	-9.7	(-47.1,29.0)
White	5	2	40.0	(11.8, 76.9)	19	12	63.2	(41.0, 80.9)	0.5151	23.2	(-25.8,63.9)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	21	13	61.9	(40.9, 79.2)	0.5697	21.9	(-27.1,62.2)
Asia(ex Japan) + Japan	11	4	36.4	(15.2, 64.6)	13	3	23.1	(8.2, 50.3)	0.6448	-13.3	(-50.0,25.1)
BMI											
< 25 kg/m2	8	3	37.5	(13.7, 69.4)	14	7	50.0	(26.8, 73.2)	0.7241	12.5	(-32.5,52.6)
25 to < 30 kg/m2	5	2	40.0	(11.8, 76.9)	10	3	30.0	(10.8, 60.3)	0.8554	-10.0	(-60.9,39.9)
>= 30 kg/m2	3	1	33.3	(6.1, 79.2)	10	6	60.0	(31.3, 83.2)	0.6571	26.7	(-40.6,75.2)
Mutation status IL36RN											
Yes	2	1	50.0		5	4	80.0				
No	11	5	45.5		23	8	34.8				

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inf = infinity. NC = not calculable

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Table 2.3.1.1 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 1 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.48	(0.43,5.28)	1.25	(0.64,4.05) (0.61,2.59)	
Sex					0.6985
Male	2.33	(0.14,78.01)	1.62	(0.45,44.01) (0.30,8.65)	
Female	1.20	(0.28,5.28)	1.11	(0.48,3.45) (0.48,2.60)	
Age					NC
>= 50 years	inf	(0.49, inf)	inf	(0.59, inf)	
< 50 years	0.95	(0.24,3.82)	0.97	(0.45,2.41) (0.45,2.10)	
Race					0.3499
Asian	0.64	(0.11,3.77)	0.73	(0.19,2.80) (0.23,2.31)	
White	2.57	(0.30,25.16)	1.58	(0.64,14.26) (0.51,4.87)	
Region					0.3016
Europe + Africa + US	2.44	(0.29,23.51)	1.55	(0.63,12.91) (0.50,4.77)	
Asia(ex Japan) + Japan	0.53	(0.08,3.42)	0.63	(0.13,2.54) (0.18,2.24)	
BMI					0.7126
< 25 kg/m2	1.67	(0.26,11.27)	1.33	(0.47,8.24) (0.47,3.76)	
25 to < 30 kg/m2	0.64	(0.06,8.09)	0.75	(0.15,7.13) (0.18,3.14)	
>= 30 kg/m2	3.00	(0.16,102.16)	1.80	(0.49,49.29) (0.34,9.64)	
Mutation status IL36RN					
Yes					
No					

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Table 2.3.1.1 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 1 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	3	60.0	(23.1, 88.2)	8	5	62.5	(30.6, 86.3)	1.0000	2.5	(-50.3,56.5)
No	10	3	30.0	(10.8, 60.3)	20	7	35.0	(18.1, 56.7)	0.8978	5.0	(-34.3,38.4)
Baseline GPPGA pustulation subscore											
<4	10	3	30.0	(10.8, 60.3)	21	10	47.6	(28.3, 67.6)	0.4557	17.6	(-22.4,50.0)
=4	6	3	50.0	(18.8, 81.2)	13	6	46.2	(23.2, 70.9)	0.9761	-3.8	(-50.1,43.6)
Baseline GPPGA score											
=3	13	4	30.8	(12.7, 57.6)	27	14	51.9	(34.0, 69.3)	0.3527	21.1	(-14.3,49.8)
=4	3	2	66.7	(20.8, 93.9)	7	2	28.6	(8.2, 64.1)	0.3817	-38.1	(-85.4,32.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	1	16.7				
No	13	6	46.2		28	15	53.6				
Background treatment prior to randomization											
Yes	7	1	14.3	(2.6, 51.3)	14	6	42.9	(21.4, 67.4)	0.3604	28.6	(-17.5,62.3)
No	9	5	55.6	(26.7, 81.1)	20	10	50.0	(29.9, 70.1)	0.9358	-5.6	(-42.9,34.9)
Pain VAS score at baseline											
<= 40	0	0	na		0	0	na				
> 40	16	6	37.5		34	16	47.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	16	6	37.5		31	13	41.9				

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Table 2.3.1.1 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 1 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.8768
Yes	1.11	(0.09,12.52)	1.04	(0.39,5.17) (0.43,2.55)	
No	1.26	(0.24,7.60)	1.17	(0.38,7.29) (0.38,3.57)	
Baseline GPPGA pustulation subscore					0.4616
<4	2.12	(0.42,12.28)	1.59	(0.61,7.00) (0.56,4.53)	
=4	0.86	(0.11,6.84)	0.92	(0.34,6.63) (0.34,2.49)	
Baseline GPPGA score					0.1094
=3	2.42	(0.59,10.82)	1.69	(0.74,7.12) (0.69,4.11)	
=4	0.20	(0.01,4.67)	0.43	(0.05,5.05) (0.10,1.77)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.2491
Yes	4.50	(0.45,120.37)	3.00	(0.61,79.25) (0.44,20.31)	
No	0.80	(0.15,4.13)	0.90	(0.43,2.49) (0.43,1.87)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.1.1 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 1 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	6	40.0		26	13	50.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.1.1 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 1 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

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Table 2.3.1.2 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 4 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	16	2	12.5	(3.5, 36.0)	34	18	52.9	(36.7, 68.5)	0.0107	40.4	(6.9,61.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	5	38.5	(17.7, 64.5)	0.2865	38.5	(-30.2,70.8)
Female	13	2	15.4	(4.3, 42.2)	21	13	61.9	(40.9, 79.2)	0.0103	46.5	(7.3,71.5)
Age											
>= 50 years	2	0	0.0	(0.0, 65.8)	10	5	50.0	(23.7, 76.3)	0.3246	50.0	(-36.6,84.1)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	11	2	18.2	(5.1, 47.7)	15	8	53.3	(30.1, 75.2)	0.1096	35.2	(-6.5,66.3)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	11	2	18.2	(5.1, 47.7)	13	7	53.8	(29.1, 76.8)	0.0856	35.7	(-4.9,69.4)
BMI											
< 25 kg/m2	8	1	12.5		14	8	57.1				
25 to < 30 kg/m2	5	1	20.0		10	4	40.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	11	2	18.2		23	10	43.5				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.2 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 4 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.88	(1.64,55.80)	4.24	(1.08,47.71) (1.12,16.09)	
Sex					NC
Male	inf	(0.41, inf)	inf	(0.44, inf)	
Female	8.94	(1.58,67.82)	4.02	(1.16,38.60) (1.08,15.04)	
Age					NC
>= 50 years	inf	(0.34, inf)	inf	(0.46, inf)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	5.14	(0.81,42.41)	2.93	(0.90,24.10) (0.77,11.20)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	5.25	(0.78,44.55)	2.96	(0.87,27.72) (0.77,11.43)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.1.2 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 4 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	0	0.0	(0.0, 43.4)	8	7	87.5	(52.9, 97.8)	0.0023	87.5	(32.8,99.7)
No	10	2	20.0	(5.7, 51.0)	20	8	40.0	(21.9, 61.3)	0.3645	20.0	(-19.0,50.5)
Baseline GPPGA pustulation subscore											
<4	10	0	0.0	(0.0, 27.8)	21	13	61.9	(40.9, 79.2)	0.0015	61.9	(18.7,81.9)
=4	6	2	33.3	(9.7, 70.0)	13	5	38.5	(17.7, 64.5)	0.9480	5.1	(-45.0,47.5)
Baseline GPPGA score											
=3	13	2	15.4	(4.3, 42.2)	27	17	63.0	(44.2, 78.5)	0.0099	47.6	(8.6,70.9)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	13	2	15.4		28	16	57.1				
Background treatment prior to randomization											
Yes	7	1	14.3	(2.6, 51.3)	14	6	42.9	(21.4, 67.4)	0.3604	28.6	(-17.5,62.3)
No	9	1	11.1	(2.0, 43.5)	20	12	60.0	(38.7, 78.1)	0.0235	48.9	(4.3,74.1)
Pain VAS score at baseline											
<= 40	0	0	na		0	0	na				
> 40	16	2	12.5		34	18	52.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	16	2	12.5		31	16	51.6				

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inf = infinity. NC = not calculable

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Table 2.3.1.2 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 4 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					NC
Yes	inf	(4.32, inf)	inf	(1.77, inf)	
No	2.67	(0.45,21.86)	2.00	(0.59,16.51) (0.52,7.72)	
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.79, inf)	inf	(1.80, inf)	
=4	1.25	(0.15,12.77)	1.15	(0.32,7.12) (0.31,4.34)	
Baseline GPPGA score					NC
=3	9.35	(1.76,68.85)	4.09	(1.16,47.89) (1.11,15.13)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6677
Yes	4.50	(0.45,120.37)	3.00	(0.61,79.25) (0.44,20.31)	
No	12.00	(1.39,288.51)	5.40	(1.05,154.72) (0.82,35.47)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.1.2 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 4 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	2	13.3		26	15	57.7			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.2 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 4 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.3 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 12 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	16	2	12.5	(3.5, 36.0)	34	15	44.1	(28.9, 60.5)	0.0356	31.6	(1.3,53.1)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	5	38.5	(17.7, 64.5)	0.2865	38.5	(-30.2,70.8)
Female	13	2	15.4	(4.3, 42.2)	21	10	47.6	(28.3, 67.6)	0.0727	32.2	(-2.5,59.2)
Age											
>= 50 years	2	1	50.0	(9.5, 90.5)	10	3	30.0	(10.8, 60.3)	0.8554	-20.0	(-78.9,44.5)
< 50 years	14	1	7.1	(1.3, 31.5)	24	12	50.0	(31.4, 68.6)	0.0089	42.9	(7.1,65.5)
Race											
Asian	11	2	18.2	(5.1, 47.7)	15	8	53.3	(30.1, 75.2)	0.1096	35.2	(-6.5,66.3)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	11	2	18.2		13	7	53.8				
BMI											
< 25 kg/m2	8	0	0.0		14	6	42.9				
25 to < 30 kg/m2	5	2	40.0		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	11	1	9.1		23	9	39.1				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.3 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 12 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.53	(1.15,39.55)	3.53	(1.02,36.29) (0.91,13.62)	
Sex					NC
Male	inf	(0.41, inf)	inf	(0.44, inf)	
Female	5.00	(0.90,38.49)	3.10	(0.89,33.53) (0.80,11.96)	
Age					0.0598
>= 50 years	0.43	(0.01,22.09)	0.60	(0.11,15.65) (0.11,3.21)	
< 50 years	13.00	(1.72,300.12)	7.00	(1.14,196.33) (1.02,48.25)	
Race					NC
Asian	5.14	(0.81,42.41)	2.93	(0.90,24.10) (0.77,11.20)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.3 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 12 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	1	20.0		8	4	50.0				
No	10	1	10.0		20	8	40.0				
Baseline GPPGA pustulation subscore											
<4	10	1	10.0	(1.8, 40.4)	21	11	52.4	(32.4, 71.7)	0.0317	42.4	(2.9,67.7)
=4	6	1	16.7	(3.0, 56.4)	13	4	30.8	(12.7, 57.6)	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score											
=3	13	2	15.4	(4.3, 42.2)	27	14	51.9	(34.0, 69.3)	0.0349	36.5	(1.7,61.4)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	13	2	15.4		28	12	42.9				
Background treatment prior to randomization											
Yes	7	0	0.0	(0.0, 35.4)	14	5	35.7	(16.3, 61.2)	0.1047	35.7	(-6.3,64.9)
No	9	2	22.2	(6.3, 54.7)	20	10	50.0	(29.9, 70.1)	0.3268	27.8	(-12.5,59.5)
Pain VAS score at baseline											
<= 40	0	0	na		0	0	na				
> 40	16	2	12.5		34	15	44.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	16	2	12.5		31	13	41.9				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.3 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 12 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4551
<4	9.90	(1.21,236.97)	5.24	(1.04,146.58) (0.78,35.15)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					NC
=3	5.92	(1.14,43.92)	3.37	(1.02,37.16) (0.90,12.69)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.01, inf)	inf	(0.80, inf)	
No	3.50	(0.58,28.61)	2.25	(0.73,24.37) (0.61,8.24)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.3 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 12 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	2	13.3		26	13	50.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.1.3 Proportion of patients with Pain VAS score drop by at least 30 from baseline overall and by subgroup at week 12 - RS, patients with Pain VAS score >= 30 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.3.2 FACIT-Fatigue score

Table 2.3.2.1 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	8	47.1	(26.2, 69.0)	34	24	70.6	(53.8, 83.2)	0.1251	23.5	(-5.5,50.9)
Sex											
Male	3	2	66.7	(20.8, 93.9)	13	9	69.2	(42.4, 87.3)	1.0000	2.6	(-45.9,63.1)
Female	14	6	42.9	(21.4, 67.4)	21	15	71.4	(50.0, 86.2)	0.1233	28.6	(-5.6,58.9)
Age											
>= 50 years	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
< 50 years	14	8	57.1	(32.6, 78.6)	24	18	75.0	(55.1, 88.0)	0.3466	17.9	(-13.4,49.0)
Race											
Asian	12	5	41.7	(19.3, 68.0)	16	10	62.5	(38.6, 81.5)	0.4198	20.8	(-17.7,55.1)
White	5	3	60.0	(23.1, 88.2)	18	14	77.8	(54.8, 91.0)	0.5044	17.8	(-25.6,64.5)
Region											
Europe + Africa + US	5	3	60.0	(23.1, 88.2)	20	15	75.0	(53.1, 88.8)	0.7535	15.0	(-26.7,61.9)
Asia(ex Japan) + Japan	12	5	41.7	(19.3, 68.0)	14	9	64.3	(38.8, 83.7)	0.2920	22.6	(-18.0,58.1)
BMI											
< 25 kg/m2	8	4	50.0	(21.5, 78.5)	14	8	57.1	(32.6, 78.6)	0.8060	7.1	(-36.0,49.1)
25 to < 30 kg/m2	6	3	50.0	(18.8, 81.2)	10	8	80.0	(49.0, 94.3)	0.3511	30.0	(-20.4,72.9)
>= 30 kg/m2	3	1	33.3	(6.1, 79.2)	10	8	80.0	(49.0, 94.3)	0.2291	46.7	(-19.3,90.5)
Mutation status IL36RN											
Yes	2	2	100.0		5	5	100.0				
No	12	5	41.7		23	15	65.2				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.1 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.70	(0.78,9.24)	1.50	(0.91,3.57) (0.87,2.60)	
Sex					0.3994
Male	1.13	(0.03,18.73)	1.04	(0.50,7.57) (0.43,2.50)	
Female	3.33	(0.77,14.41)	1.67	(0.91,4.56) (0.86,3.23)	
Age					NC
>= 50 years	inf	(0.87, inf)	inf	(0.74, inf)	
< 50 years	2.25	(0.52,9.54)	1.31	(0.81,2.65) (0.79,2.18)	
Race					0.7910
Asian	2.33	(0.48,11.43)	1.50	(0.70,4.23) (0.69,3.24)	
White	2.33	(0.21,20.81)	1.30	(0.71,9.16) (0.61,2.76)	
Region					0.7037
Europe + Africa + US	2.00	(0.19,16.99)	1.25	(0.69,8.26) (0.59,2.67)	
Asia(ex Japan) + Japan	2.52	(0.49,13.10)	1.54	(0.72,4.66) (0.71,3.35)	
BMI					0.6927
< 25 kg/m2	1.33	(0.21,8.29)	1.14	(0.49,4.36) (0.50,2.62)	
25 to < 30 kg/m2	4.00	(0.37,44.70)	1.60	(0.71,8.56) (0.68,3.77)	
>= 30 kg/m2	8.00	(0.35,261.87)	2.40	(0.76,71.17) (0.47,12.25)	
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.1 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	4	80.0	(37.6, 96.4)	8	7	87.5	(52.9, 97.8)	0.8491	7.5	(-41.0,59.6)
No	11	4	36.4	(15.2, 64.6)	20	13	65.0	(43.3, 81.9)	0.1437	28.6	(-9.9,60.9)
Baseline GPPGA pustulation subscore											
<4	11	4	36.4	(15.2, 64.6)	21	14	66.7	(45.4, 82.8)	0.1280	30.3	(-7.1,61.6)
=4	6	4	66.7	(30.0, 90.3)	13	10	76.9	(49.7, 91.8)	0.8190	10.3	(-32.2,58.0)
Baseline GPPGA score											
=3	14	6	42.9	(21.4, 67.4)	27	21	77.8	(59.2, 89.4)	0.0445	34.9	(0.6,63.2)
=4	3	2	66.7	(20.8, 93.9)	7	3	42.9	(15.8, 75.0)	0.8467	-23.8	(-76.0,47.1)
Baseline plaque psoriasis											
Yes	3	2	66.7		6	5	83.3				
No	14	6	42.9		28	19	67.9				
Background treatment prior to randomization											
Yes	8	2	25.0	(7.1, 59.1)	14	10	71.4	(45.4, 88.3)	0.0460	46.4	(0.8,78.0)
No	9	6	66.7	(35.4, 87.9)	20	14	70.0	(48.1, 85.5)	0.9358	3.3	(-31.5,43.0)
Pain VAS score at baseline											
<= 40	1	0	0.0		1	0	0.0				
> 40	16	8	50.0		33	24	72.7				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	8	47.1		31	21	67.7				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.1 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.3296
Yes	1.75	(0.04,77.41)	1.09	(0.59,3.04) (0.66,1.82)	
No	3.25	(0.67,16.25)	1.79	(0.84,8.02) (0.77,4.16)	
Baseline GPPGA pustulation subscore					0.3893
<4	3.50	(0.72,17.37)	1.83	(0.86,7.69) (0.79,4.24)	
=4	1.67	(0.15,15.43)	1.15	(0.60,5.36) (0.61,2.19)	
Baseline GPPGA score					0.1272
=3	4.67	(1.10,19.57)	1.81	(1.01,7.40) (0.96,3.43)	
=4	0.38	(0.01,7.81)	0.64	(0.15,5.97) (0.20,2.07)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.1487
Yes	7.50	(0.98,66.75)	2.86	(1.01,30.89) (0.82,9.92)	
No	1.17	(0.18,6.52)	1.05	(0.61,2.46) (0.61,1.81)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.1 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	8	53.3		25	18	72.0			
Mild	1	0	0.0		6	4	66.7			
Moderate	0	0	na		1	1	100.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.2.1 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.2.2 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	2	11.8	(3.3, 34.3)	34	18	52.9	(36.7, 68.5)	0.0059	41.2	(9.3,62.1)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	5	38.5	(17.7, 64.5)	0.2865	38.5	(-30.2,70.8)
Female	14	2	14.3	(4.0, 39.9)	21	13	61.9	(40.9, 79.2)	0.0065	47.6	(11.6,72.1)
Age											
>= 50 years	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	12	2	16.7	(4.7, 44.8)	16	8	50.0	(28.0, 72.0)	0.0833	33.3	(-4.2,63.7)
White	5	0	0.0	(0.0, 43.4)	18	10	55.6	(33.7, 75.4)	0.0450	55.6	(0.8,78.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	20	10	50.0	(29.9, 70.1)	0.1802	50.0	(-6.6,73.3)
Asia(ex Japan) + Japan	12	2	16.7	(4.7, 44.8)	14	8	57.1	(32.6, 78.6)	0.0401	40.5	(1.8,71.9)
BMI											
< 25 kg/m2	8	1	12.5		14	8	57.1				
25 to < 30 kg/m2	6	1	16.7		10	4	40.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		23	9	39.1				

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Table 2.3.2.2 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.44	(1.77,59.45)	4.50	(1.11,50.69) (1.18,17.18)	
Sex					NC
Male	inf	(0.41, inf)	inf	(0.44, inf)	
Female	9.75	(1.74,73.35)	4.33	(1.21,41.89) (1.15,16.32)	
Age					NC
>= 50 years	inf	(0.60, inf)	inf	(0.59, inf)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	5.00	(0.81,40.46)	3.00	(0.89,24.67) (0.77,11.65)	
White	inf	(1.65, inf)	inf	(1.01, inf)	
Region					NC
Europe + Africa + US	inf	(1.36, inf)	inf	(0.88, inf)	
Asia(ex Japan) + Japan	6.67	(1.02,54.80)	3.43	(1.05,28.12) (0.89,13.15)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.2.2 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	0	0.0		8	7	87.5				
No	11	2	18.2		20	7	35.0				
Baseline GPPGA pustulation subscore											
<4	11	0	0.0	(0.0, 25.9)	21	12	57.1	(36.5, 75.5)	0.0029	57.1	(16.5,78.2)
=4	6	2	33.3	(9.7, 70.0)	13	6	46.2	(23.2, 70.9)	0.8190	12.8	(-38.0,54.7)
Baseline GPPGA score											
=3	14	2	14.3	(4.0, 39.9)	27	16	59.3	(40.7, 75.5)	0.0071	45.0	(7.7,68.1)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	14	2	14.3		28	15	53.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	14	5	35.7	(16.3, 61.2)	0.3387	23.2	(-19.0,56.3)
No	9	1	11.1	(2.0, 43.5)	20	13	65.0	(43.3, 81.9)	0.0140	53.9	(12.4,78.7)
Pain VAS score at baseline											
<= 40	1	0	0.0		1	0	0.0				
> 40	16	2	12.5		33	18	54.5				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	2	11.8		31	16	51.6				

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Table 2.3.2.2 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.42, inf)	inf	(1.93, inf)	
=4	1.71	(0.21,17.04)	1.38	(0.40,15.12) (0.39,4.95)	
Baseline GPPGA score					NC
=3	8.73	(1.68,63.80)	4.15	(1.15,40.01) (1.11,15.54)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6050
Yes	3.89	(0.39,104.83)	2.86	(0.53,74.19) (0.40,20.35)	
No	14.86	(1.69,354.97)	5.85	(1.15,170.76) (0.90,38.17)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.2.2 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	2	13.3		25	15	60.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Table 2.3.2.2 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Table 2.3.2.3 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	2	11.8	(3.3, 34.3)	34	19	55.9	(39.5, 71.1)	0.0043	44.1	(10.2,64.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	7	53.8	(29.1, 76.8)	0.1724	53.8	(-21.2,81.9)
Female	14	2	14.3	(4.0, 39.9)	21	12	57.1	(36.5, 75.5)	0.0138	42.9	(6.2,68.0)
Age											
>= 50 years	3	1	33.3	(6.1, 79.2)	10	5	50.0	(23.7, 76.3)	0.9951	16.7	(-47.7,67.4)
< 50 years	14	1	7.1	(1.3, 31.5)	24	14	58.3	(38.8, 75.5)	0.0025	51.2	(17.5,72.7)
Race											
Asian	12	2	16.7	(4.7, 44.8)	16	10	62.5	(38.6, 81.5)	0.0180	45.8	(6.2,73.8)
White	5	0	0.0	(0.0, 43.4)	18	9	50.0	(29.0, 71.0)	0.0537	50.0	(-8.0,74.2)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	20	10	50.0	(29.9, 70.1)	0.1802	50.0	(-6.6,73.3)
Asia(ex Japan) + Japan	12	2	16.7	(4.7, 44.8)	14	9	64.3	(38.8, 83.7)	0.0164	47.6	(8.7,76.7)
BMI											
< 25 kg/m2	8	0	0.0		14	8	57.1				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		23	10	43.5				

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Table 2.3.2.3 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.50	(1.99,66.80)	4.75	(1.30,50.69) (1.25,18.06)	
Sex					NC
Male	inf	(0.75, inf)	inf	(0.72, inf)	
Female	8.00	(1.44,60.33)	4.00	(1.14,36.10) (1.05,15.21)	
Age					0.1970
>= 50 years	2.00	(0.11,70.07)	1.50	(0.37,39.93) (0.27,8.34)	
< 50 years	18.20	(2.38,415.48)	8.17	(1.54,236.07) (1.20,55.63)	
Race					NC
Asian	8.33	(1.32,66.63)	3.75	(1.16,40.56) (1.00,14.05)	
White	inf	(1.33, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.36, inf)	inf	(0.88, inf)	
Asia(ex Japan) + Japan	9.00	(1.35,73.84)	3.86	(1.15,28.12) (1.03,14.50)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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inf = infinity. NC = not calculable

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Table 2.3.2.3 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	1	20.0		8	7	87.5				
No	11	1	9.1		20	8	40.0				
Baseline GPPGA pustulation subscore											
<4	11	1	9.1	(1.6, 37.7)	21	13	61.9	(40.9, 79.2)	0.0064	52.8	(10.1,76.6)
=4	6	1	16.7	(3.0, 56.4)	13	6	46.2	(23.2, 70.9)	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score											
=3	14	2	14.3	(4.0, 39.9)	27	16	59.3	(40.7, 75.5)	0.0071	45.0	(7.7,68.1)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	14	2	14.3		28	15	53.6				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	14	6	42.9	(21.4, 67.4)	0.0426	42.9	(1.3,71.1)
No	9	2	22.2	(6.3, 54.7)	20	13	65.0	(43.3, 81.9)	0.0625	42.8	(-1.3,71.5)
Pain VAS score at baseline											
<= 40	1	0	0.0		1	0	0.0				
> 40	16	2	12.5		33	19	57.6				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	2	11.8		31	17	54.8				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.3 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.5096
<4	16.25	(1.97,380.15)	6.81	(1.20,197.23) (1.02,45.47)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					NC
=3	8.73	(1.68,63.80)	4.15	(1.15,40.01) (1.11,15.54)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.60, inf)	inf	(1.02, inf)	
No	6.50	(1.03,52.57)	2.93	(0.96,26.28) (0.83,10.35)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.3 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	2	13.3		25	16	64.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.3 Proportion of patients with FACIT-Fatigue scale score improvement of at least 4 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 48 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.4 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	6	35.3	(17.3, 58.7)	33	18	54.5	(38.0, 70.2)	0.3125	19.3	(-12.3,45.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	8	66.7	(39.1, 86.2)	0.1772	66.7	(-10.1,90.5)
Female	14	6	42.9	(21.4, 67.4)	21	10	47.6	(28.3, 67.6)	0.8804	4.8	(-29.7,37.4)
Age											
>= 50 years	3	0	0.0	(0.0, 56.1)	9	5	55.6	(26.7, 81.1)	0.2338	55.6	(-16.2,86.3)
< 50 years	14	6	42.9	(21.4, 67.4)	24	13	54.2	(35.1, 72.1)	0.7171	11.3	(-22.7,42.9)
Race											
Asian	12	4	33.3	(13.8, 60.9)	15	8	53.3	(30.1, 75.2)	0.4417	20.0	(-18.9,55.1)
White	5	2	40.0	(11.8, 76.9)	18	10	55.6	(33.7, 75.4)	0.7025	15.6	(-33.7,57.6)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	20	10	50.0	(29.9, 70.1)	1.0000	10.0	(-39.2,52.2)
Asia(ex Japan) + Japan	12	4	33.3	(13.8, 60.9)	13	8	61.5	(35.5, 82.3)	0.2195	28.2	(-13.5,63.3)
BMI											
< 25 kg/m2	8	3	37.5		13	6	46.2				
25 to < 30 kg/m2	6	2	33.3		10	6	60.0				
>= 30 kg/m2	3	1	33.3		10	6	60.0				
Mutation status IL36RN											
Yes	2	1	50.0		5	3	60.0				
No	12	5	41.7		22	11	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.4 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.20	(0.64,7.74)	1.55	(0.78,5.64) (0.76,3.16)	
Sex					NC
Male	inf	(1.19, inf)	inf	(0.89, inf)	
Female	1.21	(0.30,4.98)	1.11	(0.52,2.72) (0.52,2.36)	
Age					NC
>= 50 years	inf	(0.71, inf)	inf	(0.65, inf)	
< 50 years	1.58	(0.40,6.24)	1.26	(0.64,3.28) (0.62,2.57)	
Race					0.8513
Asian	2.29	(0.45,11.94)	1.60	(0.63,6.79) (0.63,4.05)	
White	1.88	(0.22,18.57)	1.39	(0.54,15.05) (0.44,4.39)	
Region					0.6038
Europe + Africa + US	1.50	(0.18,14.72)	1.25	(0.47,13.55) (0.39,3.99)	
Asia(ex Japan) + Japan	3.20	(0.59,17.76)	1.85	(0.76,7.50) (0.74,4.58)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.2.4 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	3	60.0	(23.1, 88.2)	8	5	62.5	(30.6, 86.3)	1.0000	2.5	(-50.3,56.5)
No	11	3	27.3	(9.7, 56.6)	19	9	47.4	(27.3, 68.3)	0.4243	20.1	(-18.6,51.9)
Baseline GPPGA pustulation subscore											
<4	11	4	36.4	(15.2, 64.6)	20	11	55.0	(34.2, 74.2)	0.4152	18.6	(-19.6,52.0)
=4	6	2	33.3	(9.7, 70.0)	13	7	53.8	(29.1, 76.8)	0.4869	20.5	(-30.9,61.2)
Baseline GPPGA score											
=3	14	5	35.7	(16.3, 61.2)	26	15	57.7	(38.9, 74.5)	0.3211	22.0	(-11.6,51.2)
=4	3	1	33.3	(6.1, 79.2)	7	3	42.9	(15.8, 75.0)	0.9428	9.5	(-58.8,65.2)
Baseline plaque psoriasis											
Yes	3	1	33.3		6	5	83.3				
No	14	5	35.7		27	13	48.1				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	13	7	53.8	(29.1, 76.8)	0.1013	41.3	(-4.9,72.8)
No	9	5	55.6	(26.7, 81.1)	20	11	55.0	(34.2, 74.2)	1.0000	-0.6	(-38.1,39.5)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	16	6	37.5		33	18	54.5				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	6	35.3		30	15	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.4 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4737
Yes	1.11	(0.09,12.52)	1.04	(0.39,5.17) (0.43,2.55)	
No	2.40	(0.47,13.87)	1.74	(0.65,8.48) (0.59,5.09)	
Baseline GPPGA pustulation subscore					0.9323
<4	2.14	(0.45,10.58)	1.51	(0.68,8.02) (0.63,3.63)	
=4	2.33	(0.29,22.83)	1.62	(0.53,15.12) (0.47,5.57)	
Baseline GPPGA score					0.8207
=3	2.45	(0.62,9.98)	1.62	(0.77,7.78) (0.74,3.51)	
=4	1.50	(0.07,58.21)	1.29	(0.23,33.89) (0.21,7.89)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.1553
Yes	8.17	(0.82,209.66)	4.31	(0.86,117.06) (0.64,28.84)	
No	0.98	(0.18,5.05)	0.99	(0.48,2.94) (0.49,2.01)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.2.4 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	6	40.0		25	14	56.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	1	100.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.2.4 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 1 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.5 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	2	11.8	(3.3, 34.3)	33	18	54.5	(38.0, 70.2)	0.0049	42.8	(10.2,63.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	5	41.7	(19.3, 68.0)	0.2607	41.7	(-33.1,72.7)
Female	14	2	14.3	(4.0, 39.9)	21	13	61.9	(40.9, 79.2)	0.0065	47.6	(11.6,72.1)
Age											
>= 50 years	3	0	0.0	(0.0, 56.1)	9	5	55.6	(26.7, 81.1)	0.2338	55.6	(-16.2,86.3)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	12	2	16.7	(4.7, 44.8)	15	8	53.3	(30.1, 75.2)	0.0643	36.7	(-2.0,67.4)
White	5	0	0.0	(0.0, 43.4)	18	10	55.6	(33.7, 75.4)	0.0450	55.6	(0.8,78.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	20	10	50.0	(29.9, 70.1)	0.1802	50.0	(-6.6,73.3)
Asia(ex Japan) + Japan	12	2	16.7	(4.7, 44.8)	13	8	61.5	(35.5, 82.3)	0.0265	44.9	(5.1,76.0)
BMI											
< 25 kg/m2	8	1	12.5		13	8	61.5				
25 to < 30 kg/m2	6	1	16.7		10	4	40.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		22	9	40.9				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.5 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.00	(1.87,63.50)	4.64	(1.23,52.24) (1.22,17.68)	
Sex					NC
Male	inf	(0.46, inf)	inf	(0.48, inf)	
Female	9.75	(1.74,73.35)	4.33	(1.21,41.89) (1.15,16.32)	
Age					NC
>= 50 years	inf	(0.71, inf)	inf	(0.65, inf)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	5.71	(0.91,46.54)	3.20	(0.97,26.29) (0.83,12.35)	
White	inf	(1.65, inf)	inf	(1.01, inf)	
Region					NC
Europe + Africa + US	inf	(1.36, inf)	inf	(0.88, inf)	
Asia(ex Japan) + Japan	8.00	(1.18,66.65)	3.69	(1.14,30.24) (0.97,14.05)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.2.5 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	0	0.0		8	7	87.5				
No	11	2	18.2		19	7	36.8				
Baseline GPPGA pustulation subscore											
<4	11	0	0.0	(0.0, 25.9)	20	12	60.0	(38.7, 78.1)	0.0015	60.0	(23.4,80.9)
=4	6	2	33.3	(9.7, 70.0)	13	6	46.2	(23.2, 70.9)	0.8190	12.8	(-38.0,54.7)
Baseline GPPGA score											
=3	14	2	14.3	(4.0, 39.9)	26	16	61.5	(42.5, 77.6)	0.0069	47.3	(11.0,71.1)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	14	2	14.3		27	15	55.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	13	5	38.5	(17.7, 64.5)	0.3569	26.0	(-19.9,60.0)
No	9	1	11.1	(2.0, 43.5)	20	13	65.0	(43.3, 81.9)	0.0140	53.9	(12.4,78.7)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	16	2	12.5		33	18	54.5				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	2	11.8		30	16	53.3				

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Table 2.3.2.5 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.88, inf)	inf	(1.93, inf)	
=4	1.71	(0.21,17.04)	1.38	(0.40,15.12) (0.39,4.95)	
Baseline GPPGA score					NC
=3	9.60	(1.82,70.39)	4.31	(1.15,41.56) (1.15,16.10)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6423
Yes	4.38	(0.43,117.89)	3.08	(0.58,80.20) (0.43,21.80)	
No	14.86	(1.69,354.97)	5.85	(1.15,170.76) (0.90,38.17)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.5 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	2	13.3		25	15	60.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.5 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 4 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.6 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	1	5.9	(1.0, 27.0)	33	18	54.5	(38.0, 70.2)	0.0014	48.7	(18.4,67.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	6	50.0	(25.4, 74.6)	0.1875	50.0	(-23.9,79.1)
Female	14	1	7.1	(1.3, 31.5)	21	12	57.1	(36.5, 75.5)	0.0040	50.0	(17.1,73.0)
Age											
>= 50 years	3	0	0.0	(0.0, 56.1)	9	5	55.6	(26.7, 81.1)	0.2338	55.6	(-16.2,86.3)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	12	1	8.3	(1.5, 35.4)	15	9	60.0	(35.7, 80.2)	0.0075	51.7	(12.2,78.7)
White	5	0	0.0	(0.0, 43.4)	18	9	50.0	(29.0, 71.0)	0.0537	50.0	(-8.0,74.2)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	20	10	50.0	(29.9, 70.1)	0.1802	50.0	(-6.6,73.3)
Asia(ex Japan) + Japan	12	1	8.3	(1.5, 35.4)	13	8	61.5	(35.5, 82.3)	0.0058	53.2	(15.3,80.8)
BMI											
< 25 kg/m2	8	0	0.0		13	7	53.8				
25 to < 30 kg/m2	6	1	16.7		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		22	10	45.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.6 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	19.20	(2.78,427.04)	9.27	(1.79,271.88) (1.35,63.68)	
Sex					NC
Male	inf	(0.63, inf)	inf	(0.65, inf)	
Female	17.33	(2.19,399.77)	8.00	(1.41,227.65) (1.17,54.82)	
Age					NC
>= 50 years	inf	(0.71, inf)	inf	(0.65, inf)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	16.50	(1.82,394.11)	7.20	(1.26,201.61) (1.05,49.18)	
White	inf	(1.33, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.36, inf)	inf	(0.88, inf)	
Asia(ex Japan) + Japan	17.60	(1.83,425.05)	7.38	(1.38,205.82) (1.08,50.63)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.6 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	0	0.0		8	7	87.5				
No	11	1	9.1		19	8	42.1				
Baseline GPPGA pustulation subscore											
<4	11	0	0.0	(0.0, 25.9)	20	13	65.0	(43.3, 81.9)	0.0008	65.0	(30.5,84.6)
=4	6	1	16.7	(3.0, 56.4)	13	5	38.5	(17.7, 64.5)	0.4859	21.8	(-28.2,58.2)
Baseline GPPGA score											
=3	14	1	7.1	(1.3, 31.5)	26	16	61.5	(42.5, 77.6)	0.0013	54.4	(17.6,74.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	14	1	7.1		27	15	55.6				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	13	6	46.2	(23.2, 70.9)	0.0279	46.2	(4.0,75.5)
No	9	1	11.1	(2.0, 43.5)	20	12	60.0	(38.7, 78.1)	0.0235	48.9	(4.3,74.1)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	16	1	6.3		33	18	54.5				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	1	5.9		30	16	53.3				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.2.6 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(5.92, inf)	inf	(2.39, inf)	
=4	3.13	(0.29,88.28)	2.31	(0.45,60.18) (0.34,15.69)	
Baseline GPPGA score					NC
=3	20.80	(2.75,471.03)	8.62	(1.72,253.74) (1.27,58.35)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.79, inf)	inf	(1.05, inf)	
No	12.00	(1.39,288.51)	5.40	(1.05,154.72) (0.82,35.47)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.2.6 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	1	6.7		25	15	60.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.2.6 Proportion of patients with FACIT-Fatigue scale score improvement of at least 8 points from baseline overall and by subgroup at week 12 - RS, patients with FACIT-Fatigue scale score <= 44 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.3.3 PSS score

Table 2.3.3.1 Proportion of patients with PSS score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	0	0.0		35	0	0.0			
Sex										
Male	3	0	0.0		14	0	0.0			
Female	15	0	0.0		21	0	0.0			
Age										
>= 50 years	4	0	0.0		11	0	0.0			
< 50 years	14	0	0.0		24	0	0.0			
Race										
Asian	13	0	0.0		16	0	0.0			
White	5	0	0.0		19	0	0.0			
Region										
Europe + Africa + US	5	0	0.0		21	0	0.0			
Asia(ex Japan) + Japan	13	0	0.0		14	0	0.0			
BMI										
< 25 kg/m2	9	0	0.0		15	0	0.0			
25 to < 30 kg/m2	6	0	0.0		10	0	0.0			
>= 30 kg/m2	3	0	0.0		10	0	0.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	0	0.0		24	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.1 Proportion of patients with PSS score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Overall			
Sex			
Male			
Female			
Age			
>= 50 years			
< 50 years			
Race			
Asian			
White			
Region			
Europe + Africa + US			
Asia(ex Japan) + Japan			
BMI			
< 25 kg/m2			
25 to < 30 kg/m2			
>= 30 kg/m2			
Mutation status IL36RN			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.1 Proportion of patients with PSS score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	0	0.0		21	0	0.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	0	0.0			
=4	6	0	0.0		13	0	0.0			
Baseline GPPGA score										
=3	15	0	0.0		28	0	0.0			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	0	0.0		29	0	0.0			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	0	0.0		20	0	0.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	0	0.0		34	0	0.0			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	0	0.0		32	0	0.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.1 Proportion of patients with PSS score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.1 Proportion of patients with PSS score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	0	0.0		26	0	0.0			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.1 Proportion of patients with PSS score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.2 Proportion of patients with PSS score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	(0.0, 17.6)	35	3	8.6	(3.0, 22.4)	0.3121	8.6	(-11.7,23.1)
Sex											
Male	3	0	0.0		14	0	0.0				
Female	15	0	0.0		21	3	14.3				
Age											
>= 50 years	4	0	0.0		11	0	0.0				
< 50 years	14	0	0.0		24	3	12.5				
Race											
Asian	13	0	0.0		16	0	0.0				
White	5	0	0.0		19	3	15.8				
Region											
Europe + Africa + US	5	0	0.0		21	3	14.3				
Asia(ex Japan) + Japan	13	0	0.0		14	0	0.0				
BMI											
< 25 kg/m2	9	0	0.0		15	2	13.3				
25 to < 30 kg/m2	6	0	0.0		10	0	0.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	2	40.0				
No	12	0	0.0		24	1	4.2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.2 Proportion of patients with PSS score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.45, inf)	inf	(0.36, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.2 Proportion of patients with PSS score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	2	25.0			
No	11	0	0.0		21	1	4.8			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	2	9.1			
=4	6	0	0.0		13	1	7.7			
Baseline GPPGA score										
=3	15	0	0.0		28	3	10.7			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	0	0.0		29	3	10.3			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	0	0.0		20	3	15.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	0	0.0		34	3	8.8			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	0	0.0		32	3	9.4			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.2 Proportion of patients with PSS score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.2 Proportion of patients with PSS score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	0	0.0		26	3	11.5			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.2 Proportion of patients with PSS score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.3 Proportion of patients with PSS score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	6	17.1	(8.1, 32.7)	0.3794	11.6	(-11.8,29.2)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	1	6.7		21	3	14.3				
Age											
>= 50 years	4	0	0.0		11	1	9.1				
< 50 years	14	1	7.1		24	5	20.8				
Race											
Asian	13	1	7.7		16	2	12.5				
White	5	0	0.0		19	4	21.1				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	1	7.7		14	1	7.1				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	1	16.7		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	2	8.3				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.3 Proportion of patients with PSS score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.52	(0.46,85.94)	3.09	(0.50,78.78) (0.40,23.71)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.3 Proportion of patients with PSS score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	3	37.5			
No	11	1	9.1		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	5	22.7			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	6	21.4			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	5	17.2			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	1	10.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	6	17.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	6	18.8			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.3 Proportion of patients with PSS score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.3 Proportion of patients with PSS score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	5	19.2			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.3 Proportion of patients with PSS score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.4 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	8	22.9	(12.1, 39.0)	0.1336	17.3 (-7.8,36.0)
Sex										
Male	3	0	0.0		14	3	21.4			
Female	15	1	6.7		21	5	23.8			
Age										
>= 50 years	4	0	0.0		11	2	18.2			
< 50 years	14	1	7.1		24	6	25.0			
Race										
Asian	13	0	0.0		16	2	12.5			
White	5	1	20.0		19	6	31.6			
Region										
Europe + Africa + US	5	1	20.0		21	6	28.6			
Asia(ex Japan) + Japan	13	0	0.0		14	2	14.3			
BMI										
< 25 kg/m2	9	0	0.0		15	0	0.0			
25 to < 30 kg/m2	6	1	16.7		10	4	40.0			
>= 30 kg/m2	3	0	0.0		10	4	40.0			
Mutation status IL36RN										
Yes	2	1	50.0		5	3	60.0			
No	12	0	0.0		24	4	16.7			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.4 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.04	(0.70,118.83)	4.11	(0.72,107.24) (0.56,30.39)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.4 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	3	37.5			
No	11	0	0.0		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	7	31.8			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	0	0.0		28	8	28.6			
=4	3	1	33.3		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	2	33.3			
No	15	1	6.7		29	6	20.7			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	1	10.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	8	23.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	8	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.4 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.4 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	7	26.9			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.4 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 1 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.5 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	14	40.0	(25.6, 56.4)	0.0476	28.9	(0.2,49.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	4	28.6	(11.7, 54.6)	0.4453	28.6	(-39.3,59.3)
Female	15	2	13.3	(3.7, 37.9)	21	10	47.6	(28.3, 67.6)	0.0417	34.3	(2.6,60.4)
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	4	36.4	(15.2, 64.6)	0.2581	36.4	(-26.6,69.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	10	41.7	(24.5, 61.2)	0.0997	27.4	(-6.8,52.9)
Race											
Asian	13	2	15.4		16	6	37.5				
White	5	0	0.0		19	8	42.1				
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	2	15.4		14	6	42.9				
BMI											
< 25 kg/m2	9	1	11.1		15	6	40.0				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	2	16.7		24	7	29.2				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.5 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.33	(1.13,37.92)	3.60	(1.00,39.66) (0.92,14.14)	
Sex					NC
Male	inf	(0.26, inf)	inf	(0.29, inf)	
Female	5.91	(1.09,44.76)	3.57	(1.06,38.68) (0.91,14.00)	
Age					NC
>= 50 years	inf	(0.50, inf)	inf	(0.46, inf)	
< 50 years	4.29	(0.81,32.49)	2.92	(0.86,31.61) (0.74,11.45)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.5 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	5	62.5			
No	11	2	18.2		21	6	28.6			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0	(0.0, 24.2)	22	12	54.5	(34.7, 73.1)	0.0016	54.5 (21.1,75.6)
=4	6	2	33.3	(9.7, 70.0)	13	2	15.4	(4.3, 42.2)	0.4859	-17.9 (-64.2,23.8)
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	14	50.0	(32.6, 67.4)	0.0250	36.7 (2.5,59.7)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	2	33.3			
No	15	2	13.3		29	12	41.4			
Background treatment prior to randomization										
Yes	8	1	12.5		15	6	40.0			
No	10	1	10.0		20	8	40.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	2	12.5		34	13	38.2			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	13	40.6			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.5 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.44, inf)	inf	(1.75, inf)	
=4	0.36	(0.03,4.76)	0.46	(0.03,6.63) (0.08,2.54)	
Baseline GPPGA score					NC
=3	6.50	(1.29,47.35)	3.75	(1.06,41.33) (0.98,14.35)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.5 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.5 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.6 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 12 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	13	37.1	(23.2, 53.7)	0.0235	31.6	(4.3,50.8)
Sex											
Male	3	0	0.0		14	5	35.7				
Female	15	1	6.7		21	8	38.1				
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	4	36.4	(15.2, 64.6)	0.2581	36.4	(-26.6,69.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	9	37.5	(21.2, 57.3)	0.0631	30.4	(-1.3,53.9)
Race											
Asian	13	1	7.7		16	5	31.3				
White	5	0	0.0		19	8	42.1				
Region											
Europe + Africa + US	5	0	0.0		21	9	42.9				
Asia(ex Japan) + Japan	13	1	7.7		14	4	28.6				
BMI											
< 25 kg/m2	9	0	0.0		15	6	40.0				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	6	25.0				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.6 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 12 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	10.05	(1.47,227.19)	6.69	(1.06,184.67) (0.95,47.13)	
Sex					
Male					
Female					
Age					NC
>= 50 years	inf	(0.50, inf)	inf	(0.46, inf)	
< 50 years	7.80	(1.02,184.62)	5.25	(0.98,140.82) (0.74,37.20)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.6 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 12 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0		8	5	62.5				
No	11	1	9.1		21	5	23.8				
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	11	50.0	(30.7, 69.3)	0.0040	50.0	(14.9,72.3)
=4	6	1	16.7	(3.0, 56.4)	13	2	15.4	(4.3, 42.2)	1.0000	-1.3	(-47.5,34.4)
Baseline GPPGA score											
=3	15	1	6.7	(1.2, 29.8)	28	13	46.4	(29.5, 64.2)	0.0128	39.8	(7.0,61.6)
=4	3	0	0.0		7	0	0.0				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	1	6.7		29	11	37.9				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	4	26.7	(10.9, 52.0)	0.1387	26.7	(-15.8,55.1)
No	10	1	10.0	(1.8, 40.4)	20	9	45.0	(25.8, 65.8)	0.0791	35.0	(-5.0,61.9)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	1	6.3		34	13	38.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	1	5.6		32	12	37.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.3.6 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 12 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(3.72, inf)	inf	(1.54, inf)	
=4	0.91	(0.06,31.93)	0.92	(0.09,24.95) (0.10,8.31)	
Baseline GPPGA score					NC
=3	12.13	(1.68,277.32)	6.96	(1.13,195.39) (1.01,48.21)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(0.75, inf)	inf	(0.60, inf)	
No	7.36	(0.89,179.46)	4.50	(0.86,122.26) (0.66,30.74)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.3.6 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 12 - RS (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	11	42.3			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.6 Proportion of patients with PSS pain score of 0 overall and by subgroup at week 12 - RS (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.7 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	3	8.6	(3.0, 22.4)	0.8564	3.0	(-19.5,19.0)
Sex											
Male	3	0	0.0		14	1	7.1				
Female	15	1	6.7		21	2	9.5				
Age											
>= 50 years	4	0	0.0		11	0	0.0				
< 50 years	14	1	7.1		24	3	12.5				
Race											
Asian	13	1	7.7		16	2	12.5				
White	5	0	0.0		19	1	5.3				
Region											
Europe + Africa + US	5	0	0.0		21	1	4.8				
Asia(ex Japan) + Japan	13	1	7.7		14	2	14.3				
BMI											
< 25 kg/m2	9	0	0.0		15	0	0.0				
25 to < 30 kg/m2	6	1	16.7		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	0	0.0				
No	12	1	8.3		24	2	8.3				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.7 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.7 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	1	9.1		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	3	13.6			
=4	6	1	16.7		13	0	0.0			
Baseline GPPGA score										
=3	15	1	6.7		28	3	10.7			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	2	6.9			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	3	15.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	3	8.8			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	3	9.4			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.7 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.7 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	3	11.5			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.7 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.8 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	6	17.1	(8.1, 32.7)	0.3794	11.6 (-11.8,29.2)
Sex										
Male	3	0	0.0		14	2	14.3			
Female	15	1	6.7		21	4	19.0			
Age										
>= 50 years	4	0	0.0		11	0	0.0			
< 50 years	14	1	7.1		24	6	25.0			
Race										
Asian	13	1	7.7		16	2	12.5			
White	5	0	0.0		19	4	21.1			
Region										
Europe + Africa + US	5	0	0.0		21	4	19.0			
Asia(ex Japan) + Japan	13	1	7.7		14	2	14.3			
BMI										
< 25 kg/m2	9	0	0.0		15	3	20.0			
25 to < 30 kg/m2	6	1	16.7		10	2	20.0			
>= 30 kg/m2	3	0	0.0		10	1	10.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	2	40.0			
No	12	1	8.3		24	2	8.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.8 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.52	(0.46,85.94)	3.09	(0.50,78.78) (0.40,23.71)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.8 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	2	25.0			
No	11	1	9.1		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	5	22.7			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	6	21.4			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	5	17.2			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	6	30.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	6	17.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	6	18.8			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.8 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.8 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	6	23.1			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.3.8 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.3.9 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	9	25.7	(14.2, 42.1)	0.3121	14.6	(-11.7,34.8)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	2	13.3		21	6	28.6				
Age											
>= 50 years	4	1	25.0		11	2	18.2				
< 50 years	14	1	7.1		24	7	29.2				
Race											
Asian	13	2	15.4		16	4	25.0				
White	5	0	0.0		19	5	26.3				
Region											
Europe + Africa + US	5	0	0.0		21	6	28.6				
Asia(ex Japan) + Japan	13	2	15.4		14	3	21.4				
BMI											
< 25 kg/m2	9	0	0.0		15	5	33.3				
25 to < 30 kg/m2	6	2	33.3		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	3	30.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	5	20.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.9 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.77	(0.56,20.53)	2.31	(0.61,22.59) (0.56,9.60)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.9 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	4	50.0			
No	11	1	9.1		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	8	36.4			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	9	32.1	(17.9, 50.7)	0.3199	18.8 (-10.7,42.5)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	8	27.6			
Background treatment prior to randomization										
Yes	8	0	0.0		15	3	20.0			
No	10	2	20.0		20	6	30.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	2	12.5		34	9	26.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	9	28.1			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.9 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	3.08	(0.59,23.32)	2.41	(0.69,22.04) (0.60,9.76)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.9 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	7	26.9			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.9 Proportion of patients with PSS redness score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.10 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	10	28.6	(16.3, 45.1)	0.4283	11.9	(-15.5,33.7)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	3	20.0		21	6	28.6				
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	3	27.3	(9.7, 56.6)	0.3537	27.3	(-33.5,61.0)
< 50 years	14	3	21.4	(7.6, 47.6)	24	7	29.2	(14.9, 49.2)	0.7171	7.7	(-24.8,35.2)
Race											
Asian	13	2	15.4		16	5	31.3				
White	5	1	20.0		19	5	26.3				
Region											
Europe + Africa + US	5	1	20.0		21	6	28.6				
Asia(ex Japan) + Japan	13	2	15.4		14	4	28.6				
BMI											
< 25 kg/m2	9	1	11.1		15	3	20.0				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	1	50.0		5	3	60.0				
No	12	2	16.7		24	6	25.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.10 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.00	(0.48,10.17)	1.71	(0.58,7.65) (0.54,5.46)	
Sex					
Male					
Female					
Age					NC
>= 50 years	inf	(0.32, inf)	inf	(0.31, inf)	
< 50 years	1.51	(0.32,8.46)	1.36	(0.41,8.55) (0.42,4.43)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.10 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	4	50.0			
No	11	2	18.2		21	5	23.8			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	9	40.9			
=4	6	3	50.0		13	1	7.7			
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	10	35.7	(20.7, 54.2)	0.1417	22.4 (-9.8,46.0)
=4	3	1	33.3	(6.1, 79.2)	7	0	0.0	(0.0, 35.4)	0.2974	-33.3 (-90.6,22.4)
Baseline plaque psoriasis										
Yes	3	0	0.0		6	2	33.3			
No	15	3	20.0		29	8	27.6			
Background treatment prior to randomization										
Yes	8	1	12.5		15	3	20.0			
No	10	2	20.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	3	18.8		34	10	29.4			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	3	16.7		32	10	31.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.10 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	3.61	(0.71,27.04)	2.68	(0.77,29.05) (0.67,10.67)	
=4	0.00	(0.00,3.86)	0.00	(0.00,5.95)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.10 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	8	30.8			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.10 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.11 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	18	51.4	(35.6, 67.0)	0.0067	40.3	(9.6,60.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	2	13.3	(3.7, 37.9)	21	12	57.1	(36.5, 75.5)	0.0079	43.8	(10.2,68.7)
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	6	54.5	(28.0, 78.7)	0.0794	54.5	(-10.7,83.3)
< 50 years	14	2	14.3	(4.0, 39.9)	24	12	50.0	(31.4, 68.6)	0.0344	35.7	(2.1,60.6)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	8	50.0	(28.0, 72.0)	0.0742	34.6	(-3.1,64.7)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	7	50.0	(26.8, 73.2)	0.0819	34.6	(-2.4,65.7)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	9	60.0	(35.7, 80.2)	0.0276	48.9	(3.6,76.6)
25 to < 30 kg/m2	6	1	16.7	(3.0, 56.4)	10	4	40.0	(16.8, 68.7)	0.4435	23.3	(-29.5,64.1)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	5	50.0	(23.7, 76.3)	0.2112	50.0	(-21.5,82.6)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	10	41.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.11 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.47	(1.80,59.33)	4.63	(1.21,52.13) (1.21,17.78)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	8.67	(1.58,64.88)	4.29	(1.19,38.68) (1.12,16.41)	
Age					NC
>= 50 years	inf	(1.05, inf)	inf	(0.83, inf)	
< 50 years	6.00	(1.13,44.82)	3.50	(1.02,31.61) (0.91,13.42)	
Race					NC
Asian	5.50	(0.91,44.05)	3.25	(0.95,26.73) (0.83,12.74)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	5.50	(0.86,45.20)	3.25	(0.93,30.47) (0.82,12.90)	
BMI					NC
< 25 kg/m2	12.00	(1.27,295.27)	5.40	(1.12,151.26) (0.81,35.87)	
25 to < 30 kg/m2	3.33	(0.28,97.86)	2.40	(0.39,62.54) (0.34,16.76)	
>= 30 kg/m2	inf	(0.60, inf)	inf	(0.59, inf)	
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.3.11 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0	(0.0, 39.0)	8	7	87.5	(52.9, 97.8)	0.0011	87.5	(37.7,99.7)
No	11	2	18.2	(5.1, 47.7)	21	8	38.1	(20.8, 59.1)	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	13	59.1	(38.7, 76.7)	0.0010	59.1	(21.1,79.3)
=4	6	2	33.3	(9.7, 70.0)	13	5	38.5	(17.7, 64.5)	0.9480	5.1	(-45.0,47.5)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	17	60.7	(42.4, 76.4)	0.0051	47.4	(11.6,69.6)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	2	13.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	6	40.0	(19.8, 64.3)	0.3175	27.5	(-15.9,59.1)
No	10	1	10.0	(1.8, 40.4)	20	12	60.0	(38.7, 78.1)	0.0104	50.0	(9.8,74.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	16	50.0				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.11 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					NC
Yes	inf	(5.30, inf)	inf	(2.02, inf)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					NC
<4	inf	(5.29, inf)	inf	(2.07, inf)	
=4	1.25	(0.15,12.77)	1.15	(0.32,7.12) (0.31,4.34)	
Baseline GPPGA score					NC
=3	10.05	(1.96,72.58)	4.55	(1.27,54.41) (1.21,17.12)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6491
Yes	4.67	(0.49,122.42)	3.20	(0.62,84.14) (0.46,22.16)	
No	13.50	(1.60,320.72)	6.00	(1.13,171.88) (0.90,39.86)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.11 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.11 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.12 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	15	42.9	(28.0, 59.1)	0.0067	37.3	(9.5,56.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	1	6.7	(1.2, 29.8)	21	9	42.9	(24.5, 63.5)	0.0200	36.2	(5.0,61.6)
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	5	45.5	(21.3, 72.0)	0.2581	45.5	(-15.3,76.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	10	41.7	(24.5, 61.2)	0.0301	34.5	(2.1,58.1)
Race											
Asian	13	1	7.7		16	8	50.0				
White	5	0	0.0		19	7	36.8				
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	1	7.7		14	7	50.0				
BMI											
< 25 kg/m2	9	0	0.0		15	7	46.7				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	9	37.5				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.12 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 12 – RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	12.75	(1.88,285.68)	7.71	(1.11,217.83) (1.11,53.83)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	10.50	(1.35,247.16)	6.43	(1.12,173.93) (0.91,45.50)	
Age					NC
>= 50 years	inf	(0.74, inf)	inf	(0.64, inf)	
< 50 years	9.29	(1.23,217.63)	5.83	(1.02,158.80) (0.83,40.88)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.12 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0		8	6	75.0				
No	11	1	9.1		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	12	54.5	(34.7, 73.1)	0.0016	54.5	(21.1,75.6)
=4	6	1	16.7	(3.0, 56.4)	13	3	23.1	(8.2, 50.3)	0.9119	6.4	(-41.0,42.7)
Baseline GPPGA score											
=3	15	1	6.7	(1.2, 29.8)	28	14	50.0	(32.6, 67.4)	0.0070	43.3	(11.6,64.3)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	1	6.7		29	13	44.8				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	5	33.3	(15.2, 58.3)	0.1229	33.3	(-6.9,61.6)
No	10	1	10.0	(1.8, 40.4)	20	10	50.0	(29.9, 70.1)	0.0383	40.0	(2.0,66.3)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	1	6.3		34	14	41.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	1	5.6		32	15	46.9				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.12 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.44, inf)	inf	(1.75, inf)	
=4	1.50	(0.12,46.97)	1.38	(0.17,35.82) (0.18,10.71)	
Baseline GPPGA score					NC
=3	14.00	(1.94,318.36)	7.50	(1.13,213.18) (1.09,51.64)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.07, inf)	inf	(0.81, inf)	
No	9.00	(1.08,217.16)	5.00	(1.03,138.20) (0.74,33.78)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.12 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	12	46.2			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.12 Proportion of patients with PSS burning score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.13 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	4	11.4	(4.5, 26.0)	0.7740	5.9	(-17.0,22.7)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	1	6.7		21	1	4.8				
Age											
>= 50 years	4	0	0.0		11	1	9.1				
< 50 years	14	1	7.1		24	3	12.5				
Race											
Asian	13	0	0.0		16	0	0.0				
White	5	1	20.0		19	4	21.1				
Region											
Europe + Africa + US	5	1	20.0		21	4	19.0				
Asia(ex Japan) + Japan	13	0	0.0		14	0	0.0				
BMI											
< 25 kg/m2	9	0	0.0		15	2	13.3				
25 to < 30 kg/m2	6	1	16.7		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	1	50.0		5	2	40.0				
No	12	0	0.0		24	1	4.2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.13 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.13 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	2	25.0			
No	11	0	0.0		21	1	4.8			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	4	18.2			
=4	6	1	16.7		13	0	0.0			
Baseline GPPGA score										
=3	15	0	0.0		28	4	14.3			
=4	3	1	33.3		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	1	6.7		29	4	13.8			
Background treatment prior to randomization										
Yes	8	0	0.0		15	0	0.0			
No	10	1	10.0		20	4	20.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	4	11.8			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	4	12.5			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.13 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.13 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	3	11.5			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.13 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.14 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	0	0.0	(0.0, 17.6)	35	6	17.1	(8.1, 32.7)	0.0829	17.1 (-3.8,33.6)
Sex										
Male	3	0	0.0		14	2	14.3			
Female	15	0	0.0		21	4	19.0			
Age										
>= 50 years	4	0	0.0		11	2	18.2			
< 50 years	14	0	0.0		24	4	16.7			
Race										
Asian	13	0	0.0		16	0	0.0			
White	5	0	0.0		19	6	31.6			
Region										
Europe + Africa + US	5	0	0.0		21	6	28.6			
Asia(ex Japan) + Japan	13	0	0.0		14	0	0.0			
BMI										
< 25 kg/m2	9	0	0.0		15	3	20.0			
25 to < 30 kg/m2	6	0	0.0		10	1	10.0			
>= 30 kg/m2	3	0	0.0		10	2	20.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	3	60.0			
No	12	0	0.0		24	2	8.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.14 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(1.20, inf)	inf	(0.79, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.14 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	3	37.5			
No	11	0	0.0		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	5	22.7			
=4	6	0	0.0		13	1	7.7			
Baseline GPPGA score										
=3	15	0	0.0		28	6	21.4			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	0	0.0		29	6	20.7			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	0	0.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	0	0.0		34	6	17.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	0	0.0		32	5	15.6			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.14 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.14 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	0	0.0		26	4	15.4			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.14 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.15 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	6	17.1	(8.1, 32.7)	0.7741	6.0	(-19.1,25.6)
Sex											
Male	3	0	0.0		14	3	21.4				
Female	15	2	13.3		21	3	14.3				
Age											
>= 50 years	4	1	25.0		11	1	9.1				
< 50 years	14	1	7.1		24	5	20.8				
Race											
Asian	13	2	15.4		16	2	12.5				
White	5	0	0.0		19	4	21.1				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	2	15.4		14	1	7.1				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	2	33.3		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	2	8.3				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.15 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.66	(0.31,13.00)	1.54	(0.36,17.09) (0.35,6.89)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.15 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	3	37.5			
No	11	1	9.1		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3		22	5	22.7			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	2	13.3		28	6	21.4			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	5	17.2			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	2	20.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	2	12.5		34	6	17.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	6	18.8			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.15 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.3.15 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	5	19.2			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.3.15 Proportion of patients with PSS itching score of 0 overall and by subgroup at week 12 – RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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1.2.3.4 DLQI score

1.2.3.4.1 Improvement in DLQI score

Table 2.3.4.1.1 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	7	38.9	(20.3, 61.4)	32	18	56.3	(39.3, 71.8)	0.3368	17.4	(-13.4,44.3)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	8	66.7	(39.1, 86.2)	0.1772	66.7	(-10.1,90.5)
Female	15	7	46.7	(24.8, 69.9)	20	10	50.0	(29.9, 70.1)	0.9625	3.3	(-30.2,36.3)
Age											
>= 50 years	4	2	50.0	(15.0, 85.0)	9	5	55.6	(26.7, 81.1)	0.9742	5.6	(-50.6,60.2)
< 50 years	14	5	35.7	(16.3, 61.2)	23	13	56.5	(36.8, 74.4)	0.3552	20.8	(-13.9,51.2)
Race											
Asian	13	5	38.5	(17.7, 64.5)	15	8	53.3	(30.1, 75.2)	0.5839	14.9	(-23.4,50.2)
White	5	2	40.0	(11.8, 76.9)	17	10	58.8	(36.0, 78.4)	0.6723	18.8	(-30.8,61.0)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	19	10	52.6	(31.7, 72.7)	1.0000	12.6	(-36.8,54.5)
Asia(ex Japan) + Japan	13	5	38.5	(17.7, 64.5)	13	8	61.5	(35.5, 82.3)	0.3269	23.1	(-18.9,59.5)
BMI											
< 25 kg/m2	9	3	33.3		12	6	50.0				
25 to < 30 kg/m2	6	3	50.0		10	5	50.0				
>= 30 kg/m2	3	1	33.3		10	7	70.0				
Mutation status IL36RN											
Yes	2	1	50.0		5	3	60.0				
No	12	5	41.7		21	10	47.6				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.1 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.02	(0.61,6.81)	1.45	(0.76,3.69) (0.75,2.78)	
Sex					NC
Male	inf	(1.19, inf)	inf	(0.89, inf)	
Female	1.14	(0.29,4.55)	1.07	(0.53,2.41) (0.53,2.15)	
Age					0.6172
>= 50 years	1.25	(0.09,16.64)	1.11	(0.36,6.56) (0.36,3.48)	
< 50 years	2.34	(0.58,9.77)	1.58	(0.76,6.36) (0.72,3.48)	
Race					0.9352
Asian	1.83	(0.39,8.79)	1.39	(0.60,3.98) (0.60,3.20)	
White	2.14	(0.25,21.37)	1.47	(0.57,15.93) (0.47,4.62)	
Region					0.7859
Europe + Africa + US	1.67	(0.20,16.42)	1.32	(0.50,14.26) (0.41,4.18)	
Asia(ex Japan) + Japan	2.56	(0.50,13.24)	1.60	(0.70,4.32) (0.71,3.60)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.1 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	3	50.0	(18.8, 81.2)	8	5	62.5	(30.6, 86.3)	0.7347	12.5	(-41.4,61.5)
No	11	4	36.4	(15.2, 64.6)	18	8	44.4	(24.6, 66.3)	0.7551	8.1	(-30.7,42.8)
Baseline GPPGA pustulation subscore											
<4	12	5	41.7	(19.3, 68.0)	20	11	55.0	(34.2, 74.2)	0.7043	13.3	(-23.5,47.2)
=4	6	2	33.3	(9.7, 70.0)	12	7	58.3	(32.0, 80.7)	0.4444	25.0	(-27.1,65.9)
Baseline GPPGA score											
=3	15	6	40.0	(19.8, 64.3)	25	14	56.0	(37.1, 73.3)	0.4437	16.0	(-17.2,46.1)
=4	3	1	33.3	(6.1, 79.2)	7	4	57.1	(25.0, 84.2)	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis											
Yes	3	1	33.3		6	5	83.3				
No	15	6	40.0		26	13	50.0				
Background treatment prior to randomization											
Yes	8	2	25.0	(7.1, 59.1)	13	7	53.8	(29.1, 76.8)	0.3569	28.8	(-19.9,65.1)
No	10	5	50.0	(23.7, 76.3)	19	11	57.9	(36.3, 76.9)	0.8369	7.9	(-30.5,44.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	7	43.8		32	18	56.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	7	38.9		29	16	55.2				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.1 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9739
Yes	1.67	(0.17,16.27)	1.25	(0.45,6.60) (0.48,3.28)	
No	1.40	(0.29,7.18)	1.22	(0.48,5.38) (0.48,3.12)	
Baseline GPPGA pustulation subscore					0.7039
<4	1.71	(0.39,7.73)	1.32	(0.60,4.20) (0.61,2.87)	
=4	2.80	(0.33,27.78)	1.75	(0.58,16.35) (0.51,5.98)	
Baseline GPPGA score					0.8314
=3	1.91	(0.50,7.34)	1.40	(0.72,3.82) (0.69,2.85)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.4148
Yes	3.50	(0.48,31.53)	2.15	(0.67,20.16) (0.59,7.91)	
No	1.38	(0.28,6.79)	1.16	(0.55,3.50) (0.56,2.40)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.1 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	6	37.5		24	15	62.5			
Mild	1	1	100.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.1 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.2 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	32	18	56.3	(39.3, 71.8)	0.0090	39.6	(9.3,61.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	7	58.3	(32.0, 80.7)	0.1772	58.3	(-14.2,85.0)
Female	15	3	20.0	(7.0, 45.2)	20	11	55.0	(34.2, 74.2)	0.0560	35.0	(-0.6,62.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	4	44.4	(18.9, 73.3)	0.8330	19.4	(-43.4,65.3)
< 50 years	14	2	14.3	(4.0, 39.9)	23	14	60.9	(40.8, 77.8)	0.0085	46.6	(12.1,71.1)
Race											
Asian	13	3	23.1	(8.2, 50.3)	15	9	60.0	(35.7, 80.2)	0.0704	36.9	(-2.0,68.0)
White	5	0	0.0	(0.0, 43.4)	17	9	52.9	(31.0, 73.8)	0.0519	52.9	(-0.3,77.4)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	13	8	61.5	(35.5, 82.3)	0.0611	38.5	(-1.7,70.4)
BMI											
< 25 kg/m2	9	1	11.1		12	7	58.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		21	9	42.9				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.2 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.43	(1.57,31.41)	3.38	(1.11,18.68) (1.15,9.91)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.76, inf)	
Female	4.89	(1.03,26.29)	2.75	(0.99,12.22) (0.93,8.15)	
Age					0.4511
>= 50 years	2.40	(0.16,78.01)	1.78	(0.32,46.66) (0.28,11.28)	
< 50 years	9.33	(1.71,69.42)	4.26	(1.14,47.00) (1.13,16.02)	
Race					NC
Asian	5.00	(0.92,29.36)	2.60	(0.96,12.61) (0.89,7.62)	
White	inf	(1.47, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.49, inf)	inf	(0.92, inf)	
Asia(ex Japan) + Japan	5.33	(0.92,32.72)	2.67	(0.96,14.47) (0.90,7.86)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.2 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	2	18.2	(5.1, 47.7)	18	8	44.4	(24.6, 66.3)	0.1891	26.3	(-12.2,56.4)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	20	13	65.0	(43.3, 81.9)	0.0023	56.7	(19.3,79.0)
=4	6	2	33.3	(9.7, 70.0)	12	5	41.7	(19.3, 68.0)	0.8729	8.3	(-42.6,51.5)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	25	16	64.0	(44.5, 79.8)	0.0101	44.0	(8.9,68.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		26	14	53.8				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	13	6	46.2	(23.2, 70.9)	0.1631	33.7	(-11.7,66.6)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	3	18.8		32	18	56.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		29	16	55.2				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.2 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5999
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	3.60	(0.60,29.23)	2.44	(0.72,20.15) (0.63,9.48)	
Baseline GPPGA pustulation subscore					0.1209
<4	20.43	(2.44,473.82)	7.80	(1.54,227.60) (1.16,52.35)	
=4	1.43	(0.17,14.70)	1.25	(0.35,7.71) (0.34,4.65)	
Baseline GPPGA score					NC
=3	7.11	(1.56,36.82)	3.20	(1.13,19.87) (1.12,9.18)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8947
Yes	6.00	(0.60,157.25)	3.69	(0.74,98.06) (0.54,25.31)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.2 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		24	15	62.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.2 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.3 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	32	17	53.1	(36.4, 69.1)	0.0046	42.0	(9.3,62.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	7	58.3	(32.0, 80.7)	0.1772	58.3	(-14.2,85.0)
Female	15	2	13.3	(3.7, 37.9)	20	10	50.0	(29.9, 70.1)	0.0252	36.7	(4.4,63.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	4	44.4	(18.9, 73.3)	0.8330	19.4	(-43.4,65.3)
< 50 years	14	1	7.1	(1.3, 31.5)	23	13	56.5	(36.8, 74.4)	0.0029	49.4	(12.1,71.6)
Race											
Asian	13	2	15.4	(4.3, 42.2)	15	9	60.0	(35.7, 80.2)	0.0179	44.6	(7.7,74.0)
White	5	0	0.0	(0.0, 43.4)	17	8	47.1	(26.2, 69.0)	0.0995	47.1	(-8.9,72.7)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	13	8	61.5	(35.5, 82.3)	0.0193	46.2	(7.2,75.7)
BMI											
< 25 kg/m2	9	0	0.0		12	7	58.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		21	9	42.9				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.3 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.07	(1.89,63.91)	4.78	(1.27,57.05) (1.24,18.38)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.76, inf)	
Female	6.50	(1.18,49.39)	3.75	(1.05,40.61) (0.96,14.65)	
Age					0.2724
>= 50 years	2.40	(0.16,78.01)	1.78	(0.32,46.66) (0.28,11.28)	
< 50 years	16.90	(2.20,387.70)	7.91	(1.41,226.40) (1.16,54.10)	
Race					NC
Asian	8.25	(1.31,66.10)	3.90	(1.13,29.25) (1.02,14.90)	
White	inf	(1.17, inf)	inf	(0.81, inf)	
Region					NC
Europe + Africa + US	inf	(1.22, inf)	inf	(0.84, inf)	
Asia(ex Japan) + Japan	8.80	(1.31,72.56)	4.00	(1.21,32.76) (1.04,15.36)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.1.3 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		18	8	44.4				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	20	12	60.0	(38.7, 78.1)	0.0062	51.7	(14.5,75.1)
=4	6	1	16.7	(3.0, 56.4)	12	5	41.7	(19.3, 68.0)	0.4438	25.0	(-28.1,62.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	25	15	60.0	(40.7, 76.6)	0.0052	46.7	(11.2,69.5)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		26	13	50.0				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	13	5	38.5	(17.7, 64.5)	0.0525	38.5	(-0.4,68.4)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	2	12.5		32	17	53.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		29	15	51.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.3 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4428
<4	16.50	(2.01,385.12)	7.20	(1.27,206.22) (1.07,48.64)	
=4	3.57	(0.32,100.84)	2.50	(0.50,65.50) (0.37,16.89)	
Baseline GPPGA score					NC
=3	9.75	(1.85,71.32)	4.50	(1.20,46.31) (1.19,17.00)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.29, inf)	inf	(0.86, inf)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.1.3 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		24	14	58.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.3 Proportion of patients with DLQI score improvement of at least 4 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 4 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.4 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	6	33.3	(16.3, 56.3)	32	16	50.0	(33.6, 66.4)	0.4162	16.7	(-13.4,43.2)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	8	66.7	(39.1, 86.2)	0.1772	66.7	(-10.1,90.5)
Female	15	6	40.0	(19.8, 64.3)	20	8	40.0	(21.9, 61.3)		0.0	(-34.8,32.6)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	5	55.6	(26.7, 81.1)	0.4858	30.6	(-33.9,74.1)
< 50 years	14	5	35.7	(16.3, 61.2)	23	11	47.8	(29.2, 67.0)	0.6985	12.1	(-22.0,43.0)
Race											
Asian	13	4	30.8	(12.7, 57.6)	15	7	46.7	(24.8, 69.9)	0.5839	15.9	(-21.6,51.6)
White	5	2	40.0	(11.8, 76.9)	17	9	52.9	(31.0, 73.8)	1.0000	12.9	(-36.5,55.8)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	19	9	47.4	(27.3, 68.3)	1.0000	7.4	(-41.9,49.6)
Asia(ex Japan) + Japan	13	4	30.8	(12.7, 57.6)	13	7	53.8	(29.1, 76.8)	0.2897	23.1	(-17.2,58.3)
BMI											
< 25 kg/m2	9	3	33.3		12	6	50.0				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	1	33.3		10	5	50.0				
Mutation status IL36RN											
Yes	2	1	50.0		5	2	40.0				
No	12	5	41.7		21	9	42.9				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.4 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.00	(0.59,7.00)	1.50	(0.75,4.88) (0.72,3.14)	
Sex					NC
Male	inf	(1.19, inf)	inf	(0.89, inf)	
Female	1.00	(0.25,4.14)	1.00	(0.41,2.61) (0.44,2.27)	
Age					0.6151
>= 50 years	3.75	(0.25,117.01)	2.22	(0.50,59.74) (0.37,13.38)	
< 50 years	1.65	(0.41,6.91)	1.34	(0.60,4.51) (0.59,3.05)	
Race					0.8606
Asian	1.97	(0.40,10.15)	1.52	(0.57,5.65) (0.57,4.04)	
White	1.69	(0.20,16.93)	1.32	(0.50,9.69) (0.41,4.24)	
Region					0.6134
Europe + Africa + US	1.35	(0.16,13.42)	1.18	(0.43,8.69) (0.37,3.83)	
Asia(ex Japan) + Japan	2.63	(0.50,14.12)	1.75	(0.67,6.28) (0.67,4.56)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.4 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	2	33.3	(9.7, 70.0)	8	4	50.0	(21.5, 78.5)	0.6442	16.7	(-37.9,64.1)
No	11	4	36.4	(15.2, 64.6)	18	7	38.9	(20.3, 61.4)	1.0000	2.5	(-35.5,37.5)
Baseline GPPGA pustulation subscore											
<4	12	4	33.3	(13.8, 60.9)	20	9	45.0	(25.8, 65.8)	0.7043	11.7	(-26.6,44.2)
=4	6	2	33.3	(9.7, 70.0)	12	7	58.3	(32.0, 80.7)	0.4444	25.0	(-27.1,65.9)
Baseline GPPGA score											
=3	15	5	33.3	(15.2, 58.3)	25	12	48.0	(30.0, 66.5)	0.4438	14.7	(-18.3,43.9)
=4	3	1	33.3	(6.1, 79.2)	7	4	57.1	(25.0, 84.2)	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis											
Yes	3	1	33.3		6	5	83.3				
No	15	5	33.3		26	11	42.3				
Background treatment prior to randomization											
Yes	8	2	25.0	(7.1, 59.1)	13	5	38.5	(17.7, 64.5)	0.6923	13.5	(-31.1,51.4)
No	10	4	40.0	(16.8, 68.7)	19	11	57.9	(36.3, 76.9)	0.4356	17.9	(-21.3,53.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	6	37.5		32	16	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	6	33.3		29	14	48.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.4 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.6869
Yes	2.00	(0.20,22.61)	1.50	(0.39,10.58) (0.40,5.65)	
No	1.11	(0.23,5.80)	1.07	(0.40,4.05) (0.40,2.83)	
Baseline GPPGA pustulation subscore					0.7418
<4	1.64	(0.36,7.98)	1.35	(0.53,7.44) (0.53,3.44)	
=4	2.80	(0.33,27.78)	1.75	(0.58,16.35) (0.51,5.98)	
Baseline GPPGA score					0.8581
=3	1.85	(0.48,7.47)	1.44	(0.66,5.44) (0.63,3.28)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9413
Yes	1.88	(0.25,17.64)	1.54	(0.39,9.68) (0.39,6.14)	
No	2.06	(0.41,10.66)	1.45	(0.66,7.67) (0.62,3.39)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.4 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	5	31.3		24	14	58.3			
Mild	1	1	100.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.4 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 1 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.5 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	32	18	56.3	(39.3, 71.8)	0.0090	39.6	(9.3,61.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	7	58.3	(32.0, 80.7)	0.1772	58.3	(-14.2,85.0)
Female	15	3	20.0	(7.0, 45.2)	20	11	55.0	(34.2, 74.2)	0.0560	35.0	(-0.6,62.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	4	44.4	(18.9, 73.3)	0.8330	19.4	(-43.4,65.3)
< 50 years	14	2	14.3	(4.0, 39.9)	23	14	60.9	(40.8, 77.8)	0.0085	46.6	(12.1,71.1)
Race											
Asian	13	3	23.1	(8.2, 50.3)	15	9	60.0	(35.7, 80.2)	0.0704	36.9	(-2.0,68.0)
White	5	0	0.0	(0.0, 43.4)	17	9	52.9	(31.0, 73.8)	0.0519	52.9	(-0.3,77.4)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	13	8	61.5	(35.5, 82.3)	0.0611	38.5	(-1.7,70.4)
BMI											
< 25 kg/m2	9	1	11.1		12	7	58.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		21	9	42.9				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.5 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.43	(1.57,31.41)	3.38	(1.11,18.68) (1.15,9.91)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.76, inf)	
Female	4.89	(1.03,26.29)	2.75	(0.99,12.22) (0.93,8.15)	
Age					0.4511
>= 50 years	2.40	(0.16,78.01)	1.78	(0.32,46.66) (0.28,11.28)	
< 50 years	9.33	(1.71,69.42)	4.26	(1.14,47.00) (1.13,16.02)	
Race					NC
Asian	5.00	(0.92,29.36)	2.60	(0.96,12.61) (0.89,7.62)	
White	inf	(1.47, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.49, inf)	inf	(0.92, inf)	
Asia(ex Japan) + Japan	5.33	(0.92,32.72)	2.67	(0.96,14.47) (0.90,7.86)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.1.5 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	2	18.2	(5.1, 47.7)	18	8	44.4	(24.6, 66.3)	0.1891	26.3	(-12.2,56.4)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	20	13	65.0	(43.3, 81.9)	0.0023	56.7	(19.3,79.0)
=4	6	2	33.3	(9.7, 70.0)	12	5	41.7	(19.3, 68.0)	0.8729	8.3	(-42.6,51.5)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	25	16	64.0	(44.5, 79.8)	0.0101	44.0	(8.9,68.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		26	14	53.8				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	13	6	46.2	(23.2, 70.9)	0.1631	33.7	(-11.7,66.6)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	3	18.8		32	18	56.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		29	16	55.2				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.5 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5999
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	3.60	(0.60,29.23)	2.44	(0.72,20.15) (0.63,9.48)	
Baseline GPPGA pustulation subscore					0.1209
<4	20.43	(2.44,473.82)	7.80	(1.54,227.60) (1.16,52.35)	
=4	1.43	(0.17,14.70)	1.25	(0.35,7.71) (0.34,4.65)	
Baseline GPPGA score					NC
=3	7.11	(1.56,36.82)	3.20	(1.13,19.87) (1.12,9.18)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8947
Yes	6.00	(0.60,157.25)	3.69	(0.74,98.06) (0.54,25.31)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.1.5 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		24	15	62.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.5 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 4 – RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.6 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	32	17	53.1	(36.4, 69.1)	0.0046	42.0	(9.3,62.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	7	58.3	(32.0, 80.7)	0.1772	58.3	(-14.2,85.0)
Female	15	2	13.3	(3.7, 37.9)	20	10	50.0	(29.9, 70.1)	0.0252	36.7	(4.4,63.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	4	44.4	(18.9, 73.3)	0.8330	19.4	(-43.4,65.3)
< 50 years	14	1	7.1	(1.3, 31.5)	23	13	56.5	(36.8, 74.4)	0.0029	49.4	(12.1,71.6)
Race											
Asian	13	2	15.4	(4.3, 42.2)	15	9	60.0	(35.7, 80.2)	0.0179	44.6	(7.7,74.0)
White	5	0	0.0	(0.0, 43.4)	17	8	47.1	(26.2, 69.0)	0.0995	47.1	(-8.9,72.7)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	13	8	61.5	(35.5, 82.3)	0.0193	46.2	(7.2,75.7)
BMI											
< 25 kg/m2	9	0	0.0		12	7	58.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		21	9	42.9				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.6 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.07	(1.89,63.91)	4.78	(1.27,57.05) (1.24,18.38)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.76, inf)	
Female	6.50	(1.18,49.39)	3.75	(1.05,40.61) (0.96,14.65)	
Age					0.2724
>= 50 years	2.40	(0.16,78.01)	1.78	(0.32,46.66) (0.28,11.28)	
< 50 years	16.90	(2.20,387.70)	7.91	(1.41,226.40) (1.16,54.10)	
Race					NC
Asian	8.25	(1.31,66.10)	3.90	(1.13,29.25) (1.02,14.90)	
White	inf	(1.17, inf)	inf	(0.81, inf)	
Region					NC
Europe + Africa + US	inf	(1.22, inf)	inf	(0.84, inf)	
Asia(ex Japan) + Japan	8.80	(1.31,72.56)	4.00	(1.21,32.76) (1.04,15.36)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.6 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		18	8	44.4				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	20	12	60.0	(38.7, 78.1)	0.0062	51.7	(14.5,75.1)
=4	6	1	16.7	(3.0, 56.4)	12	5	41.7	(19.3, 68.0)	0.4438	25.0	(-28.1,62.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	25	15	60.0	(40.7, 76.6)	0.0052	46.7	(11.2,69.5)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		26	13	50.0				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	13	5	38.5	(17.7, 64.5)	0.0525	38.5	(-0.4,68.4)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	2	12.5		32	17	53.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		29	15	51.7				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.6 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4428
<4	16.50	(2.01,385.12)	7.20	(1.27,206.22) (1.07,48.64)	
=4	3.57	(0.32,100.84)	2.50	(0.50,65.50) (0.37,16.89)	
Baseline GPPGA score					NC
=3	9.75	(1.85,71.32)	4.50	(1.20,46.31) (1.19,17.00)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.29, inf)	inf	(0.86, inf)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.6 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		24	14	58.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.6 Proportion of patients with DLQI score improvement of at least 5 from baseline overall and by subgroup at week 12 - RS, patients with DLQI score >= 5 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	10	55.6	(33.7, 75.4)	32	19	59.4	(42.3, 74.5)	0.8186	3.8	(-24.7,32.6)
Sex											
Male	3	1	33.3	(6.1, 79.2)	12	8	66.7	(39.1, 86.2)	0.4079	33.3	(-29.9,78.1)
Female	15	9	60.0	(35.7, 80.2)	20	11	55.0	(34.2, 74.2)	0.8636	-5.0	(-37.3,29.5)
Age											
>= 50 years	4	3	75.0	(30.1, 95.4)	9	4	44.4	(18.9, 73.3)	0.4858	-30.6	(-74.1,33.9)
< 50 years	14	7	50.0	(26.8, 73.2)	23	15	65.2	(44.9, 81.2)	0.4498	15.2	(-18.6,47.3)
Race											
Asian	13	8	61.5	(35.5, 82.3)	15	10	66.7	(41.7, 84.8)	0.8580	5.1	(-32.9,40.8)
White	5	2	40.0	(11.8, 76.9)	17	9	52.9	(31.0, 73.8)	1.0000	12.9	(-36.5,55.8)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	19	10	52.6	(31.7, 72.7)	1.0000	12.6	(-36.8,54.5)
Asia(ex Japan) + Japan	13	8	61.5	(35.5, 82.3)	13	9	69.2	(42.4, 87.3)	0.8049	7.7	(-30.1,44.0)
BMI											
< 25 kg/m2	9	4	44.4	(18.9, 73.3)	12	7	58.3	(32.0, 80.7)	0.6469	13.9	(-30.3,54.3)
25 to < 30 kg/m2	6	4	66.7	(30.0, 90.3)	10	7	70.0	(39.7, 89.2)	1.0000	3.3	(-43.0,53.2)
>= 30 kg/m2	3	2	66.7	(20.8, 93.9)	10	5	50.0	(23.7, 76.3)	0.9951	-16.7	(-67.4,47.7)
Mutation status IL36RN											
Yes	2	1	50.0		5	1	20.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.17	(0.35,3.84)	1.07	(0.65,1.97) (0.65,1.77)	
Sex					0.3812
Male	4.00	(0.22,131.46)	2.00	(0.59,56.67) (0.38,10.41)	
Female	0.81	(0.20,3.28)	0.92	(0.50,1.92) (0.52,1.63)	
Age					0.1610
>= 50 years	0.27	(0.01,3.94)	0.59	(0.18,2.20) (0.24,1.49)	
< 50 years	1.88	(0.46,7.53)	1.30	(0.73,3.02) (0.71,2.38)	
Race					0.7611
Asian	1.25	(0.25,6.26)	1.08	(0.59,2.27) (0.62,1.90)	
White	1.69	(0.20,16.93)	1.32	(0.50,9.69) (0.41,4.24)	
Region					0.8111
Europe + Africa + US	1.67	(0.20,16.42)	1.32	(0.50,14.26) (0.41,4.18)	
Asia(ex Japan) + Japan	1.41	(0.26,7.78)	1.13	(0.57,2.34) (0.64,1.97)	
BMI					0.7138
< 25 kg/m2	1.75	(0.28,10.90)	1.31	(0.54,4.33) (0.55,3.14)	
25 to < 30 kg/m2	1.17	(0.10,11.39)	1.05	(0.49,3.04) (0.52,2.11)	
>= 30 kg/m2	0.50	(0.01,8.96)	0.75	(0.25,4.27) (0.27,2.06)	
Mutation status IL36RN					
Yes					

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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	12	5	41.7		21	13	61.9			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
No				

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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	4	66.7	(30.0, 90.3)	8	3	37.5	(13.7, 69.4)	0.4163	-29.2	(-73.1,27.0)
No	11	5	45.5	(21.3, 72.0)	18	11	61.1	(38.6, 79.7)	0.4766	15.7	(-22.7,51.8)
Baseline GPPGA pustulation subscore											
<4	12	7	58.3	(32.0, 80.7)	20	11	55.0	(34.2, 74.2)	0.9024	-3.3	(-38.0,33.2)
=4	6	3	50.0	(18.8, 81.2)	12	8	66.7	(39.1, 86.2)	0.7821	16.7	(-31.5,61.5)
Baseline GPPGA score											
=3	15	9	60.0	(35.7, 80.2)	25	15	60.0	(40.7, 76.6)		0.0	(-30.8,32.1)
=4	3	1	33.3	(6.1, 79.2)	7	4	57.1	(25.0, 84.2)	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis											
Yes	3	2	66.7		6	5	83.3				
No	15	8	53.3		26	14	53.8				
Background treatment prior to randomization											
Yes	8	2	25.0	(7.1, 59.1)	13	7	53.8	(29.1, 76.8)	0.3569	28.8	(-19.9,65.1)
No	10	8	80.0	(49.0, 94.3)	19	12	63.2	(41.0, 80.9)	0.4356	-16.8	(-47.5,22.4)
Pain VAS score at baseline											
<= 40	2	1	50.0		0	0	na				
> 40	16	9	56.3		32	19	59.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	10	55.6		29	17	58.6				

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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.1870
Yes	0.30	(0.03,3.10)	0.56	(0.14,2.04) (0.20,1.62)	
No	1.89	(0.39,9.13)	1.34	(0.64,4.11) (0.64,2.83)	
Baseline GPPGA pustulation subscore					0.5329
<4	0.87	(0.19,3.86)	0.94	(0.50,2.00) (0.51,1.75)	
=4	2.00	(0.23,16.53)	1.33	(0.55,7.20) (0.55,3.26)	
Baseline GPPGA score					0.5576
=3	1.00	(0.26,3.80)	1.00	(0.59,1.96) (0.59,1.69)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.1544
Yes	3.50	(0.48,31.53)	2.15	(0.67,20.16) (0.59,7.91)	
No	0.43	(0.05,2.61)	0.79	(0.47,1.57) (0.50,1.25)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	9	56.3		24	16	66.7			
Mild	1	1	100.0		6	3	50.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.7 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 1 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.1.8 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 4 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	32	18	56.3	(39.3, 71.8)	0.0090	39.6	(9.3,61.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	7	58.3	(32.0, 80.7)	0.1772	58.3	(-14.2,85.0)
Female	15	3	20.0	(7.0, 45.2)	20	11	55.0	(34.2, 74.2)	0.0560	35.0	(-0.6,62.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	4	44.4	(18.9, 73.3)	0.8330	19.4	(-43.4,65.3)
< 50 years	14	2	14.3	(4.0, 39.9)	23	14	60.9	(40.8, 77.8)	0.0085	46.6	(12.1,71.1)
Race											
Asian	13	3	23.1	(8.2, 50.3)	15	9	60.0	(35.7, 80.2)	0.0704	36.9	(-2.0,68.0)
White	5	0	0.0	(0.0, 43.4)	17	9	52.9	(31.0, 73.8)	0.0519	52.9	(-0.3,77.4)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	13	8	61.5	(35.5, 82.3)	0.0611	38.5	(-1.7,70.4)
BMI											
< 25 kg/m2	9	1	11.1		12	7	58.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		21	9	42.9				

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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.8 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 4 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.43	(1.57,31.41)	3.38	(1.11,18.68) (1.15,9.91)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.76, inf)	
Female	4.89	(1.03,26.29)	2.75	(0.99,12.22) (0.93,8.15)	
Age					0.4511
>= 50 years	2.40	(0.16,78.01)	1.78	(0.32,46.66) (0.28,11.28)	
< 50 years	9.33	(1.71,69.42)	4.26	(1.14,47.00) (1.13,16.02)	
Race					NC
Asian	5.00	(0.92,29.36)	2.60	(0.96,12.61) (0.89,7.62)	
White	inf	(1.47, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.49, inf)	inf	(0.92, inf)	
Asia(ex Japan) + Japan	5.33	(0.92,32.72)	2.67	(0.96,14.47) (0.90,7.86)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.8 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 4 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	2	18.2	(5.1, 47.7)	18	8	44.4	(24.6, 66.3)	0.1891	26.3	(-12.2,56.4)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	20	13	65.0	(43.3, 81.9)	0.0023	56.7	(19.3,79.0)
=4	6	2	33.3	(9.7, 70.0)	12	5	41.7	(19.3, 68.0)	0.8729	8.3	(-42.6,51.5)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	25	16	64.0	(44.5, 79.8)	0.0101	44.0	(8.9,68.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		26	14	53.8				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	13	6	46.2	(23.2, 70.9)	0.1631	33.7	(-11.7,66.6)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	3	18.8		32	18	56.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		29	16	55.2				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.8 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 4 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5999
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	3.60	(0.60,29.23)	2.44	(0.72,20.15) (0.63,9.48)	
Baseline GPPGA pustulation subscore					0.1209
<4	20.43	(2.44,473.82)	7.80	(1.54,227.60) (1.16,52.35)	
=4	1.43	(0.17,14.70)	1.25	(0.35,7.71) (0.34,4.65)	
Baseline GPPGA score					NC
=3	7.11	(1.56,36.82)	3.20	(1.13,19.87) (1.12,9.18)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8947
Yes	6.00	(0.60,157.25)	3.69	(0.74,98.06) (0.54,25.31)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.8 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		24	15	62.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.8 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 4 – RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.9 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	32	19	59.4	(42.3, 74.5)	0.0010	48.3	(17.3,69.2)
Sex											
Male	3	0	0.0	(0.0, 56.1)	12	7	58.3	(32.0, 80.7)	0.1772	58.3	(-14.2,85.0)
Female	15	2	13.3	(3.7, 37.9)	20	12	60.0	(38.7, 78.1)	0.0073	46.7	(13.0,71.5)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	5	55.6	(26.7, 81.1)	0.4858	30.6	(-33.9,74.1)
< 50 years	14	1	7.1	(1.3, 31.5)	23	14	60.9	(40.8, 77.8)	0.0018	53.7	(17.4,75.2)
Race											
Asian	13	2	15.4	(4.3, 42.2)	15	10	66.7	(41.7, 84.8)	0.0068	51.3	(14.2,78.4)
White	5	0	0.0	(0.0, 43.4)	17	9	52.9	(31.0, 73.8)	0.0519	52.9	(-0.3,77.4)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	13	9	69.2	(42.4, 87.3)	0.0071	53.8	(14.2,81.3)
BMI											
< 25 kg/m2	9	0	0.0		12	8	66.7				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		21	10	47.6				

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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.9 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	11.69	(2.41,82.09)	5.34	(1.56,57.05) (1.40,20.36)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.76, inf)	
Female	9.75	(1.74,73.35)	4.50	(1.19,40.60) (1.18,17.17)	
Age					0.3158
>= 50 years	3.75	(0.25,117.01)	2.22	(0.50,59.74) (0.37,13.38)	
< 50 years	20.22	(2.60,461.46)	8.52	(1.54,247.72) (1.25,57.95)	
Race					NC
Asian	11.00	(1.69,88.22)	4.33	(1.23,46.85) (1.15,16.29)	
White	inf	(1.47, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.49, inf)	inf	(0.92, inf)	
Asia(ex Japan) + Japan	12.38	(1.76,102.68)	4.50	(1.32,32.76) (1.20,16.94)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.1.9 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	7	87.5				
No	11	1	9.1		18	8	44.4				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	20	13	65.0	(43.3, 81.9)	0.0023	56.7	(19.3,79.0)
=4	6	1	16.7	(3.0, 56.4)	12	6	50.0	(25.4, 74.6)	0.3018	33.3	(-19.7,69.5)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	25	16	64.0	(44.5, 79.8)	0.0026	50.7	(16.2,73.4)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		26	15	57.7				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	13	6	46.2	(23.2, 70.9)	0.0279	46.2	(4.0,75.5)
No	10	2	20.0	(5.7, 51.0)	19	13	68.4	(46.0, 84.6)	0.0211	48.4	(4.3,75.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	16	2	12.5		32	19	59.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		29	17	58.6				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.9 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4836
<4	20.43	(2.44,473.82)	7.80	(1.54,227.60) (1.16,52.35)	
=4	5.00	(0.45,137.29)	3.00	(0.65,80.27) (0.46,19.59)	
Baseline GPPGA score					NC
=3	11.56	(2.17,84.44)	4.80	(1.36,46.31) (1.28,18.03)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.79, inf)	inf	(1.05, inf)	
No	8.67	(1.37,69.38)	3.42	(1.12,30.65) (0.95,12.26)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.9 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		24	16	66.7			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.9 Proportion of patients with DLQI daily activities score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI daily activities score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.10 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	7	41.2	(21.6, 64.0)	33	20	60.6	(43.7, 75.3)	0.3097	19.4	(-10.9,46.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	9	69.2	(42.4, 87.3)	0.0605	69.2	(-8.8,90.9)
Female	14	7	50.0	(26.8, 73.2)	20	11	55.0	(34.2, 74.2)	0.9074	5.0	(-29.1,39.2)
Age											
>= 50 years	4	3	75.0	(30.1, 95.4)	10	6	60.0	(31.3, 83.2)	0.8826	-15.0	(-60.2,47.1)
< 50 years	13	4	30.8	(12.7, 57.6)	23	14	60.9	(40.8, 77.8)	0.0993	30.1	(-6.4,59.3)
Race											
Asian	12	5	41.7	(19.3, 68.0)	15	8	53.3	(30.1, 75.2)	0.6235	11.7	(-27.1,48.4)
White	5	2	40.0	(11.8, 76.9)	18	12	66.7	(43.7, 83.7)	0.3548	26.7	(-22.4,67.3)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	20	12	60.0	(38.7, 78.1)	0.5522	20.0	(-29.3,60.8)
Asia(ex Japan) + Japan	12	5	41.7	(19.3, 68.0)	13	8	61.5	(35.5, 82.3)	0.4937	19.9	(-22.9,56.4)
BMI											
< 25 kg/m2	9	3	33.3	(12.1, 64.6)	13	10	76.9	(49.7, 91.8)	0.0559	43.6	(-1.0,76.3)
25 to < 30 kg/m2	5	3	60.0	(23.1, 88.2)	10	5	50.0	(23.7, 76.3)	0.8671	-10.0	(-58.1,44.4)
>= 30 kg/m2	3	1	33.3	(6.1, 79.2)	10	5	50.0	(23.7, 76.3)	0.9951	16.7	(-47.7,67.4)
Mutation status IL36RN											
Yes	2	1	50.0		5	4	80.0				
No	11	5	45.5		22	11	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.10 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.20	(0.65,7.50)	1.47	(0.82,4.01) (0.78,2.77)	
Sex					NC
Male	inf	(1.34, inf)	inf	(0.90, inf)	
Female	1.22	(0.30,5.01)	1.10	(0.56,2.43) (0.57,2.12)	
Age					0.1265
>= 50 years	0.50	(0.02,7.02)	0.80	(0.34,5.61) (0.37,1.71)	
< 50 years	3.50	(0.80,16.13)	1.98	(0.90,8.32) (0.82,4.76)	
Race					0.7097
Asian	1.60	(0.33,7.88)	1.28	(0.56,3.61) (0.56,2.91)	
White	3.00	(0.34,29.63)	1.67	(0.68,15.05) (0.54,5.12)	
Region					0.9825
Europe + Africa + US	2.25	(0.27,21.87)	1.50	(0.60,13.55) (0.48,4.65)	
Asia(ex Japan) + Japan	2.24	(0.43,11.86)	1.48	(0.65,3.95) (0.67,3.27)	
BMI					0.3367
< 25 kg/m2	6.67	(0.93,48.77)	2.31	(0.98,10.02) (0.87,6.09)	
25 to < 30 kg/m2	0.67	(0.06,6.67)	0.83	(0.30,4.60) (0.32,2.15)	
>= 30 kg/m2	2.00	(0.11,70.07)	1.50	(0.37,39.93) (0.27,8.34)	
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.10 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	3	50.0	(18.8, 81.2)	8	7	87.5	(52.9, 97.8)	0.2159	37.5	(-17.9,79.2)
No	10	4	40.0	(16.8, 68.7)	19	8	42.1	(23.1, 63.7)	0.9872	2.1	(-36.5,38.3)
Baseline GPPGA pustulation subscore											
<4	12	6	50.0	(25.4, 74.6)	21	11	52.4	(32.4, 71.7)	0.9564	2.4	(-33.1,37.7)
=4	5	1	20.0	(3.6, 62.4)	12	9	75.0	(46.8, 91.1)	0.0671	55.0	(-2.6,86.4)
Baseline GPPGA score											
=3	14	6	42.9	(21.4, 67.4)	26	15	57.7	(38.9, 74.5)	0.4320	14.8	(-18.2,45.4)
=4	3	1	33.3	(6.1, 79.2)	7	5	71.4	(35.9, 91.8)	0.3817	38.1	(-32.0,85.4)
Baseline plaque psoriasis											
Yes	3	1	33.3		6	6	100.0				
No	14	6	42.9		27	14	51.9				
Background treatment prior to randomization											
Yes	8	3	37.5	(13.7, 69.4)	14	8	57.1	(32.6, 78.6)	0.4252	19.6	(-26.6,58.4)
No	9	4	44.4	(18.9, 73.3)	19	12	63.2	(41.0, 80.9)	0.4564	18.7	(-21.3,55.2)
Pain VAS score at baseline											
<= 40	2	1	50.0		0	0	na				
> 40	15	6	40.0		33	20	60.6				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	7	41.2		30	18	60.0				

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inf = infinity. NC = not calculable

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Table 2.3.4.1.10 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4255
Yes	7.00	(0.45,207.94)	1.75	(0.80,10.53) (0.75,4.06)	
No	1.09	(0.22,5.72)	1.05	(0.42,4.62) (0.42,2.65)	
Baseline GPPGA pustulation subscore					0.1918
<4	1.10	(0.25,4.78)	1.05	(0.52,2.54) (0.52,2.10)	
=4	12.00	(0.89,325.69)	3.75	(0.97,109.73) (0.63,22.31)	
Baseline GPPGA score					0.6135
=3	1.82	(0.47,7.08)	1.35	(0.71,3.84) (0.68,2.68)	
=4	5.00	(0.21,174.36)	2.14	(0.53,60.12) (0.40,11.35)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9154
Yes	2.22	(0.35,14.96)	1.52	(0.57,8.28) (0.56,4.15)	
No	2.14	(0.40,11.61)	1.42	(0.69,6.90) (0.63,3.19)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.4.1.10 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	5	33.3		25	18	72.0			
Mild	1	1	100.0		6	1	16.7			
Moderate	0	0	na		1	1	100.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.10 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.11 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	2	11.8	(3.3, 34.3)	33	18	54.5	(38.0, 70.2)	0.0049	42.8	(10.2,63.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	7	53.8	(29.1, 76.8)	0.1724	53.8	(-21.2,81.9)
Female	14	2	14.3	(4.0, 39.9)	20	11	55.0	(34.2, 74.2)	0.0172	40.7	(5.7,66.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	10	5	50.0	(23.7, 76.3)	0.5457	25.0	(-37.9,68.5)
< 50 years	13	1	7.7	(1.4, 33.3)	23	13	56.5	(36.8, 74.4)	0.0054	48.8	(13.4,71.3)
Race											
Asian	12	2	16.7	(4.7, 44.8)	15	9	60.0	(35.7, 80.2)	0.0261	43.3	(5.2,72.6)
White	5	0	0.0	(0.0, 43.4)	18	9	50.0	(29.0, 71.0)	0.0537	50.0	(-8.0,74.2)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	20	10	50.0	(29.9, 70.1)	0.1802	50.0	(-6.6,73.3)
Asia(ex Japan) + Japan	12	2	16.7	(4.7, 44.8)	13	8	61.5	(35.5, 82.3)	0.0265	44.9	(5.1,76.0)
BMI											
< 25 kg/m2	9	1	11.1		13	8	61.5				
25 to < 30 kg/m2	5	1	20.0		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	11	1	9.1		22	9	40.9				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.11 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.00	(1.87,63.50)	4.64	(1.23,52.24) (1.22,17.68)	
Sex					NC
Male	inf	(0.75, inf)	inf	(0.72, inf)	
Female	7.33	(1.31,55.78)	3.85	(1.14,37.90) (1.01,14.75)	
Age					0.3330
>= 50 years	3.00	(0.21,93.71)	2.00	(0.44,53.18) (0.33,12.18)	
< 50 years	15.60	(2.01,359.93)	7.35	(1.16,210.25) (1.08,49.96)	
Race					NC
Asian	7.50	(1.17,60.72)	3.60	(1.07,26.78) (0.95,13.62)	
White	inf	(1.33, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.36, inf)	inf	(0.88, inf)	
Asia(ex Japan) + Japan	8.00	(1.18,66.65)	3.69	(1.14,30.24) (0.97,14.05)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.1.11 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	7	87.5				
No	10	1	10.0		19	7	36.8				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	21	12	57.1	(36.5, 75.5)	0.0075	48.8	(8.6,72.3)
=4	5	1	20.0	(3.6, 62.4)	12	6	50.0	(25.4, 74.6)	0.3372	30.0	(-27.9,67.9)
Baseline GPPGA score											
=3	14	2	14.3	(4.0, 39.9)	26	15	57.7	(38.9, 74.5)	0.0162	43.4	(7.5,67.1)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	14	2	14.3		27	14	51.9				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	14	5	35.7	(16.3, 61.2)	0.3387	23.2	(-19.0,56.3)
No	9	1	11.1	(2.0, 43.5)	19	13	68.4	(46.0, 84.6)	0.0067	57.3	(11.9,81.1)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	15	2	13.3		33	18	54.5				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	2	11.8		30	16	53.3				

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Table 2.3.4.1.11 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4564
<4	14.67	(1.82,342.49)	6.86	(1.18,195.16) (1.01,46.43)	
=4	4.00	(0.34,114.27)	2.50	(0.56,66.92) (0.40,15.77)	
Baseline GPPGA score					NC
=3	8.18	(1.56,60.10)	4.04	(1.09,41.56) (1.07,15.19)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.5791
Yes	3.89	(0.39,104.83)	2.86	(0.53,74.19) (0.40,20.35)	
No	17.33	(1.91,413.83)	6.16	(1.16,181.37) (0.95,40.07)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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inf = infinity. NC = not calculable

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Table 2.3.4.1.11 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	2	13.3		25	16	64.0			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.11 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.12 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	1	5.9	(1.0, 27.0)	33	19	57.6	(40.8, 72.8)	0.0006	51.7	(22.9,70.3)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	7	53.8	(29.1, 76.8)	0.1724	53.8	(-21.2,81.9)
Female	14	1	7.1	(1.3, 31.5)	20	12	60.0	(38.7, 78.1)	0.0017	52.9	(16.9,75.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	10	5	50.0	(23.7, 76.3)	0.5457	25.0	(-37.9,68.5)
< 50 years	13	0	0.0	(0.0, 22.8)	23	14	60.9	(40.8, 77.8)	0.0003	60.9	(31.4,80.7)
Race											
Asian	12	1	8.3	(1.5, 35.4)	15	10	66.7	(41.7, 84.8)	0.0021	58.3	(19.2,83.0)
White	5	0	0.0	(0.0, 43.4)	18	9	50.0	(29.0, 71.0)	0.0537	50.0	(-8.0,74.2)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	20	10	50.0	(29.9, 70.1)	0.1802	50.0	(-6.6,73.3)
Asia(ex Japan) + Japan	12	1	8.3	(1.5, 35.4)	13	9	69.2	(42.4, 87.3)	0.0018	60.9	(23.7,86.4)
BMI											
< 25 kg/m2	9	0	0.0		13	8	61.5				
25 to < 30 kg/m2	5	1	20.0		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	11	0	0.0		22	10	45.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.12 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	21.71	(3.12,481.59)	9.79	(1.99,290.12) (1.43,67.02)	
Sex					NC
Male	inf	(0.75, inf)	inf	(0.72, inf)	
Female	19.50	(2.42,449.52)	8.40	(1.54,240.56) (1.23,57.43)	
Age					NC
>= 50 years	3.00	(0.21,93.71)	2.00	(0.44,53.18) (0.33,12.18)	
< 50 years	inf	(6.24, inf)	inf	(2.20, inf)	
Race					NC
Asian	22.00	(2.36,519.90)	8.00	(1.54,229.61) (1.18,54.04)	
White	inf	(1.33, inf)	inf	(0.91, inf)	
Region					NC
Europe + Africa + US	inf	(1.36, inf)	inf	(0.88, inf)	
Asia(ex Japan) + Japan	24.75	(2.46,589.79)	8.31	(1.54,238.32) (1.23,56.17)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.12 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	7	87.5				
No	10	0	0.0		19	8	42.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	21	13	61.9	(40.9, 79.2)	0.0050	53.6	(14.7,76.3)
=4	5	0	0.0	(0.0, 43.4)	12	6	50.0	(25.4, 74.6)	0.0672	50.0	(-2.8,78.9)
Baseline GPPGA score											
=3	14	1	7.1	(1.3, 31.5)	26	16	61.5	(42.5, 77.6)	0.0013	54.4	(17.6,74.7)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	14	1	7.1		27	15	55.6				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	14	6	42.9	(21.4, 67.4)	0.0426	42.9	(1.3,71.1)
No	9	1	11.1	(2.0, 43.5)	19	13	68.4	(46.0, 84.6)	0.0067	57.3	(11.9,81.1)
Pain VAS score at baseline											
<= 40	2	0	0.0		0	0	na				
> 40	15	1	6.7		33	19	57.6				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	1	5.9		30	17	56.7				

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inf = infinity. NC = not calculable

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Table 2.3.4.1.12 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	17.88	(2.19,414.84)	7.43	(1.38,215.14) (1.10,49.98)	
=4	inf	(1.19, inf)	inf	(0.83, inf)	
Baseline GPPGA score					NC
=3	20.80	(2.75,471.03)	8.62	(1.72,253.74) (1.27,58.35)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.60, inf)	inf	(1.02, inf)	
No	17.33	(1.91,413.83)	6.16	(1.16,181.37) (0.95,40.07)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.1.12 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	15	1	6.7		25	16	64.0			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.12 Proportion of patients with DLQI leisure score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI leisure score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.13 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	9	52.9	(31.0, 73.8)	26	14	53.8	(35.5, 71.2)	0.9948	0.9	(-29.4,31.6)
Sex											
Male	3	0	0.0	(0.0, 56.1)	9	4	44.4	(18.9, 73.3)	0.2636	44.4	(-29.8,78.8)
Female	14	9	64.3	(38.8, 83.7)	17	10	58.8	(36.0, 78.4)	0.8186	-5.5	(-40.0,29.7)
Age											
>= 50 years	3	3	100.0	(43.9, 100.0)	8	3	37.5	(13.7, 69.4)	0.0941	-62.5	(-91.5,14.9)
< 50 years	14	6	42.9	(21.4, 67.4)	18	11	61.1	(38.6, 79.7)	0.4327	18.3	(-17.7,50.9)
Race											
Asian	12	7	58.3	(32.0, 80.7)	12	6	50.0	(25.4, 74.6)	0.8388	-8.3	(-48.9,34.4)
White	5	2	40.0	(11.8, 76.9)	14	8	57.1	(32.6, 78.6)	0.5821	17.1	(-35.8,62.2)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	15	8	53.3	(30.1, 75.2)	0.9499	13.3	(-37.2,58.3)
Asia(ex Japan) + Japan	12	7	58.3	(32.0, 80.7)	11	6	54.5	(28.0, 78.7)	0.9634	-3.8	(-44.0,39.0)
BMI											
< 25 kg/m2	9	6	66.7	(35.4, 87.9)	9	5	55.6	(26.7, 81.1)	0.7752	-11.1	(-54.9,36.1)
25 to < 30 kg/m2	5	3	60.0	(23.1, 88.2)	8	4	50.0	(21.5, 78.5)	0.8553	-10.0	(-61.1,46.3)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	9	5	55.6	(26.7, 81.1)	0.2338	55.6	(-16.2,86.3)
Mutation status IL36RN											
Yes	2	1	50.0		4	3	75.0				
No	11	6	54.5		17	9	52.9				

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Table 2.3.4.1.13 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.04	(0.29,3.63)	1.02	(0.56,2.05) (0.57,1.80)	
Sex					NC
Male	inf	(0.46, inf)	inf	(0.49, inf)	
Female	0.79	(0.17,3.56)	0.92	(0.47,1.79) (0.52,1.60)	
Age					0.0218
>= 50 years	0.00	(0.00,1.15)	0.38	(0.09,1.24) (0.15,0.92)	
< 50 years	2.10	(0.48,9.09)	1.43	(0.71,3.48) (0.70,2.90)	
Race					0.4684
Asian	0.71	(0.13,3.81)	0.86	(0.34,1.94) (0.41,1.80)	
White	2.00	(0.22,20.71)	1.43	(0.53,11.72) (0.45,4.58)	
Region					0.6135
Europe + Africa + US	1.71	(0.19,17.58)	1.33	(0.49,10.96) (0.41,4.31)	
Asia(ex Japan) + Japan	0.86	(0.15,4.80)	0.94	(0.37,2.08) (0.45,1.92)	
BMI					NC
< 25 kg/m2	0.63	(0.08,4.65)	0.83	(0.33,1.98) (0.40,1.76)	
25 to < 30 kg/m2	0.67	(0.05,7.34)	0.83	(0.24,3.20) (0.31,2.26)	
>= 30 kg/m2	inf	(0.71, inf)	inf	(0.65, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.1.13 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	3	50.0	(18.8, 81.2)	6	4	66.7	(30.0, 90.3)	0.7744	16.7	(-44.7,69.7)
No	10	6	60.0	(31.3, 83.2)	15	8	53.3	(30.1, 75.2)	0.8102	-6.7	(-44.5,34.7)
Baseline GPPGA pustulation subscore											
<4	11	6	54.5	(28.0, 78.7)	16	8	50.0	(28.0, 72.0)	0.9197	-4.5	(-41.7,34.3)
=4	6	3	50.0	(18.8, 81.2)	10	6	60.0	(31.3, 83.2)	0.8247	10.0	(-40.3,57.5)
Baseline GPPGA score											
=3	14	8	57.1		20	12	60.0				
=4	3	1	33.3		6	2	33.3				
Baseline plaque psoriasis											
Yes	3	1	33.3		6	3	50.0				
No	14	8	57.1		20	11	55.0				
Background treatment prior to randomization											
Yes	7	3	42.9	(15.8, 75.0)	11	6	54.5	(28.0, 78.7)	0.7262	11.7	(-36.5,55.9)
No	10	6	60.0	(31.3, 83.2)	15	8	53.3	(30.1, 75.2)	0.8102	-6.7	(-44.5,34.7)
Pain VAS score at baseline											
<= 40	1	1	100.0		0	0	na				
> 40	16	8	50.0		26	14	53.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	9	52.9		23	11	47.8				

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Table 2.3.4.1.13 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5079
Yes	2.00	(0.17,25.42)	1.33	(0.38,5.12) (0.50,3.55)	
No	0.76	(0.14,4.08)	0.89	(0.40,2.03) (0.44,1.78)	
Baseline GPPGA pustulation subscore					0.6586
<4	0.83	(0.17,4.10)	0.92	(0.39,2.15) (0.44,1.90)	
=4	1.50	(0.17,13.03)	1.20	(0.44,8.53) (0.47,3.09)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.5661
Yes	1.60	(0.21,12.27)	1.27	(0.46,9.09) (0.46,3.50)	
No	0.76	(0.14,4.08)	0.89	(0.40,2.03) (0.44,1.78)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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inf = infinity. NC = not calculable

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Table 2.3.4.1.13 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	8	50.0		19	11	57.9			
Mild	1	1	100.0		5	2	40.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.13 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.14 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	3	17.6	(6.2, 41.0)	26	13	50.0	(32.1, 67.9)	0.0419	32.4	(0.7,56.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	9	3	33.3	(12.1, 64.6)	0.3767	33.3	(-37.1,70.7)
Female	14	3	21.4	(7.6, 47.6)	17	10	58.8	(36.0, 78.4)	0.0423	37.4	(1.3,66.6)
Age											
>= 50 years	3	1	33.3	(6.1, 79.2)	8	4	50.0	(21.5, 78.5)	0.9097	16.7	(-51.6,70.7)
< 50 years	14	2	14.3	(4.0, 39.9)	18	9	50.0	(29.0, 71.0)	0.0412	35.7	(1.5,63.8)
Race											
Asian	12	3	25.0	(8.9, 53.2)	12	7	58.3	(32.0, 80.7)	0.1259	33.3	(-8.6,67.6)
White	5	0	0.0	(0.0, 43.4)	14	6	42.9	(21.4, 67.4)	0.0897	42.9	(-13.6,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	15	6	40.0	(19.8, 64.3)	0.2392	40.0	(-11.4,67.7)
Asia(ex Japan) + Japan	12	3	25.0	(8.9, 53.2)	11	7	63.6	(35.4, 84.8)	0.0959	38.6	(-6.1,72.3)
BMI											
< 25 kg/m2	9	1	11.1		9	4	44.4				
25 to < 30 kg/m2	5	2	40.0		8	4	50.0				
>= 30 kg/m2	3	0	0.0		9	5	55.6				
Mutation status IL36RN											
Yes	2	0	0.0		4	4	100.0				
No	11	2	18.2		17	7	41.2				

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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.14 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.67	(1.08,23.71)	2.83	(1.01,21.66) (0.95,8.48)	
Sex					NC
Male	inf	(0.28, inf)	inf	(0.30, inf)	
Female	5.24	(1.03,29.44)	2.75	(1.03,12.05) (0.93,8.08)	
Age					0.4532
>= 50 years	2.00	(0.10,72.86)	1.50	(0.30,39.76) (0.26,8.58)	
< 50 years	6.00	(1.04,46.68)	3.50	(1.03,28.09) (0.89,13.69)	
Race					NC
Asian	4.20	(0.70,26.71)	2.33	(0.78,14.35) (0.78,6.94)	
White	inf	(0.94, inf)	inf	(0.75, inf)	
Region					NC
Europe + Africa + US	inf	(0.85, inf)	inf	(0.69, inf)	
Asia(ex Japan) + Japan	5.25	(0.82,34.86)	2.55	(0.88,15.59) (0.87,7.47)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.14 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		6	5	83.3				
No	10	2	20.0		15	6	40.0				
Baseline GPPGA pustulation subscore											
<4	11	1	9.1	(1.6, 37.7)	16	9	56.3	(33.2, 76.9)	0.0148	47.2	(8.0,74.0)
=4	6	2	33.3	(9.7, 70.0)	10	4	40.0	(16.8, 68.7)	0.8833	6.7	(-45.6,52.2)
Baseline GPPGA score											
=3	14	3	21.4		20	12	60.0				
=4	3	0	0.0		6	1	16.7				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	14	3	21.4		20	10	50.0				
Background treatment prior to randomization											
Yes	7	1	14.3	(2.6, 51.3)	11	4	36.4	(15.2, 64.6)	0.4603	22.1	(-26.1,59.8)
No	10	2	20.0	(5.7, 51.0)	15	9	60.0	(35.7, 80.2)	0.0778	40.0	(-3.5,70.7)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	16	3	18.8		26	13	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	3	17.6		23	11	47.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.14 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.1718
<4	12.86	(1.45,309.80)	6.19	(1.16,171.81) (0.91,42.12)	
=4	1.33	(0.15,14.54)	1.20	(0.30,8.57) (0.31,4.69)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8919
Yes	3.43	(0.30,98.00)	2.55	(0.40,66.01) (0.35,18.36)	
No	6.00	(0.91,49.94)	3.00	(0.95,21.91) (0.81,11.08)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.14 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		19	10	52.6			
Mild	1	0	0.0		5	2	40.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.14 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.15 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	17	2	11.8	(3.3, 34.3)	26	12	46.2	(28.8, 64.5)	0.0238	34.4	(5.0,57.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	9	3	33.3	(12.1, 64.6)	0.3767	33.3	(-37.1,70.7)
Female	14	2	14.3	(4.0, 39.9)	17	9	52.9	(31.0, 73.8)	0.0349	38.7	(2.6,67.1)
Age											
>= 50 years	3	1	33.3		8	4	50.0				
< 50 years	14	1	7.1		18	8	44.4				
Race											
Asian	12	2	16.7		12	7	58.3				
White	5	0	0.0		14	5	35.7				
Region											
Europe + Africa + US	5	0	0.0		15	5	33.3				
Asia(ex Japan) + Japan	12	2	16.7		11	7	63.6				
BMI											
< 25 kg/m2	9	0	0.0		9	3	33.3				
25 to < 30 kg/m2	5	2	40.0		8	4	50.0				
>= 30 kg/m2	3	0	0.0		9	5	55.6				
Mutation status IL36RN											
Yes	2	0	0.0		4	3	75.0				
No	11	1	9.1		17	7	41.2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.15 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.43	(1.27,46.92)	3.92	(1.06,35.44) (1.00,15.38)	
Sex					NC
Male	inf	(0.28, inf)	inf	(0.30, inf)	
Female	6.75	(1.15,52.78)	3.71	(1.05,29.20) (0.95,14.43)	
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.15 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		6	4	66.7				
No	10	1	10.0		15	6	40.0				
Baseline GPPGA pustulation subscore											
<4	11	1	9.1	(1.6, 37.7)	16	9	56.3	(33.2, 76.9)	0.0148	47.2	(8.0,74.0)
=4	6	1	16.7	(3.0, 56.4)	10	3	30.0	(10.8, 60.3)	0.7551	13.3	(-38.0,54.5)
Baseline GPPGA score											
=3	14	2	14.3		20	11	55.0				
=4	3	0	0.0		6	1	16.7				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	14	2	14.3		20	9	45.0				
Background treatment prior to randomization											
Yes	7	0	0.0	(0.0, 35.4)	11	4	36.4	(15.2, 64.6)	0.1045	36.4	(-11.9,69.2)
No	10	2	20.0	(5.7, 51.0)	15	8	53.3	(30.1, 75.2)	0.1213	33.3	(-8.4,65.4)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	16	2	12.5		26	12	46.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	17	2	11.8		23	10	43.5				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.15 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.3855
<4	12.86	(1.45,309.80)	6.19	(1.16,171.81) (0.91,42.12)	
=4	2.14	(0.16,67.02)	1.80	(0.23,46.78) (0.24,13.63)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(0.95, inf)	inf	(0.76, inf)	
No	4.57	(0.70,38.28)	2.67	(0.83,21.91) (0.71,10.05)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.15 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		19	9	47.4			
Mild	1	0	0.0		5	2	40.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.15 Proportion of patients with DLQI personal relationships score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI personal relationships score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	9	50.0	(29.0, 71.0)	33	20	60.6	(43.7, 75.3)	0.7474	10.6	(-18.0,38.7)
Sex											
Male	3	1	33.3	(6.1, 79.2)	13	8	61.5	(35.5, 82.3)	0.5718	28.2	(-35.0,73.3)
Female	15	8	53.3	(30.1, 75.2)	20	12	60.0	(38.7, 78.1)	0.7353	6.7	(-26.7,39.9)
Age											
>= 50 years	4	2	50.0	(15.0, 85.0)	10	5	50.0	(23.7, 76.3)		0.0	(-54.7,54.7)
< 50 years	14	7	50.0	(26.8, 73.2)	23	15	65.2	(44.9, 81.2)	0.4498	15.2	(-18.6,47.3)
Race											
Asian	13	7	53.8	(29.1, 76.8)	16	10	62.5	(38.6, 81.5)	0.6923	8.7	(-28.4,44.0)
White	5	2	40.0	(11.8, 76.9)	17	10	58.8	(36.0, 78.4)	0.6723	18.8	(-30.8,61.0)
Region											
Europe + Africa + US	5	2	40.0	(11.8, 76.9)	19	11	57.9	(36.3, 76.9)	0.7266	17.9	(-31.4,59.2)
Asia(ex Japan) + Japan	13	7	53.8	(29.1, 76.8)	14	9	64.3	(38.8, 83.7)	0.7177	10.4	(-28.4,46.6)
BMI											
< 25 kg/m2	9	3	33.3	(12.1, 64.6)	13	7	53.8	(29.1, 76.8)	0.5085	20.5	(-23.6,58.3)
25 to < 30 kg/m2	6	5	83.3	(43.6, 97.0)	10	7	70.0	(39.7, 89.2)	0.7551	-13.3	(-54.5,38.0)
>= 30 kg/m2	3	1	33.3	(6.1, 79.2)	10	6	60.0	(31.3, 83.2)	0.6571	26.7	(-40.6,75.2)
Mutation status IL36RN											
Yes	2	1	50.0		5	3	60.0				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.54	(0.47,5.02)	1.21	(0.73,2.37) (0.71,2.08)	
Sex					0.5812
Male	3.20	(0.18,105.28)	1.85	(0.54,51.61) (0.35,9.68)	
Female	1.31	(0.32,5.27)	1.13	(0.61,2.35) (0.62,2.04)	
Age					0.6903
>= 50 years	1.00	(0.08,13.02)	1.00	(0.31,5.90) (0.31,3.19)	
< 50 years	1.88	(0.46,7.53)	1.30	(0.73,3.02) (0.71,2.38)	
Race					0.7227
Asian	1.43	(0.30,6.65)	1.16	(0.60,2.59) (0.62,2.18)	
White	2.14	(0.25,21.37)	1.47	(0.57,15.93) (0.47,4.62)	
Region					0.7726
Europe + Africa + US	2.06	(0.24,20.22)	1.45	(0.58,14.26) (0.46,4.53)	
Asia(ex Japan) + Japan	1.54	(0.31,7.69)	1.19	(0.60,2.76) (0.63,2.26)	
BMI					0.4346
< 25 kg/m2	2.33	(0.38,15.46)	1.62	(0.57,9.96) (0.56,4.63)	
25 to < 30 kg/m2	0.47	(0.01,6.11)	0.84	(0.40,2.03) (0.49,1.44)	
>= 30 kg/m2	3.00	(0.16,102.16)	1.80	(0.49,49.29) (0.34,9.64)	
Mutation status IL36RN Yes					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	12	6	50.0		22	14	63.6			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
No			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	3	50.0	(18.8, 81.2)	8	5	62.5	(30.6, 86.3)	0.7347	12.5	(-41.4,61.5)
No	11	6	54.5	(28.0, 78.7)	19	12	63.2	(41.0, 80.9)	0.7863	8.6	(-28.0,44.6)
Baseline GPPGA pustulation subscore											
<4	12	6	50.0	(25.4, 74.6)	21	14	66.7	(45.4, 82.8)	0.4196	16.7	(-19.2,50.1)
=4	6	3	50.0	(18.8, 81.2)	12	6	50.0	(25.4, 74.6)		0.0	(-47.6,47.6)
Baseline GPPGA score											
=3	15	8	53.3	(30.1, 75.2)	26	16	61.5	(42.5, 77.6)	0.7221	8.2	(-23.3,39.4)
=4	3	1	33.3	(6.1, 79.2)	7	4	57.1	(25.0, 84.2)	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis											
Yes	3	2	66.7		6	5	83.3				
No	15	7	46.7		27	15	55.6				
Background treatment prior to randomization											
Yes	8	3	37.5	(13.7, 69.4)	14	7	50.0	(26.8, 73.2)	0.7241	12.5	(-32.5,52.6)
No	10	6	60.0	(31.3, 83.2)	19	13	68.4	(46.0, 84.6)	0.7617	8.4	(-27.8,46.1)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	9	56.3		32	20	62.5				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	9	50.0		30	18	60.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.8968
Yes	1.67	(0.17,16.27)	1.25	(0.45,6.60) (0.48,3.28)	
No	1.43	(0.29,6.77)	1.16	(0.61,2.92) (0.61,2.19)	
Baseline GPPGA pustulation subscore					0.6302
<4	2.00	(0.44,8.91)	1.33	(0.73,3.38) (0.70,2.53)	
=4	1.00	(0.12,8.12)	1.00	(0.37,7.16) (0.38,2.66)	
Baseline GPPGA score					0.6688
=3	1.40	(0.37,5.22)	1.15	(0.66,2.33) (0.66,2.03)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7973
Yes	1.67	(0.26,11.27)	1.33	(0.47,8.24) (0.47,3.76)	
No	1.44	(0.26,7.43)	1.14	(0.63,2.88) (0.63,2.06)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	8	50.0		24	17	70.8			
Mild	1	1	100.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.16 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
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Table 2.3.4.1.17 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	33	19	57.6	(40.8, 72.8)	0.0081	40.9	(9.4,62.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	7	53.8	(29.1, 76.8)	0.1724	53.8	(-21.2,81.9)
Female	15	3	20.0	(7.0, 45.2)	20	12	60.0	(38.7, 78.1)	0.0251	40.0	(4.4,66.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	10	6	60.0	(31.3, 83.2)	0.3376	35.0	(-28.2,76.3)
< 50 years	14	2	14.3	(4.0, 39.9)	23	13	56.5	(36.8, 74.4)	0.0133	42.2	(6.8,66.7)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	11	68.8	(44.4, 85.8)	0.0181	45.7	(7.4,74.3)
White	5	0	0.0	(0.0, 43.4)	17	8	47.1	(26.2, 69.0)	0.0995	47.1	(-8.9,72.7)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	10	71.4	(45.4, 88.3)	0.0154	48.4	(8.7,77.3)
BMI											
< 25 kg/m2	9	1	11.1		13	8	61.5				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		22	11	50.0				

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Table 2.3.4.1.17 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.79	(1.67,33.02)	3.45	(1.11,18.61) (1.18,10.11)	
Sex					NC
Male	inf	(0.75, inf)	inf	(0.72, inf)	
Female	6.00	(1.25,32.26)	3.00	(1.12,16.57) (1.03,8.78)	
Age					0.6584
>= 50 years	4.50	(0.31,136.61)	2.40	(0.60,65.66) (0.41,14.11)	
< 50 years	7.80	(1.45,58.16)	3.96	(1.14,39.48) (1.04,14.99)	
Race					NC
Asian	7.33	(1.33,43.09)	2.98	(1.14,12.38) (1.05,8.48)	
White	inf	(1.17, inf)	inf	(0.81, inf)	
Region					NC
Europe + Africa + US	inf	(1.22, inf)	inf	(0.84, inf)	
Asia(ex Japan) + Japan	8.33	(1.40,51.74)	3.10	(1.21,13.49) (1.09,8.81)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.17 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	19	9	47.4	(27.3, 68.3)	0.1564	29.2	(-9.3,58.4)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	21	13	61.9	(40.9, 79.2)	0.0050	53.6	(14.7,76.3)
=4	6	2	33.3	(9.7, 70.0)	12	6	50.0	(25.4, 74.6)	0.7822	16.7	(-35.2,58.9)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	26	16	61.5	(42.5, 77.6)	0.0151	41.5	(6.6,65.9)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		27	15	55.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	14	7	50.0	(26.8, 73.2)	0.1408	37.5	(-8.5,68.7)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		32	18	56.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		30	17	56.7				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.1.17 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5418
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	4.05	(0.69,32.39)	2.61	(0.80,20.73) (0.68,9.95)	
Baseline GPPGA pustulation subscore					0.1705
<4	17.88	(2.19,414.84)	7.43	(1.38,215.14) (1.10,49.98)	
=4	2.00	(0.24,20.07)	1.50	(0.44,16.35) (0.42,5.32)	
Baseline GPPGA score					NC
=3	6.40	(1.43,32.89)	3.08	(1.07,19.12) (1.07,8.85)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8404
Yes	7.00	(0.72,179.83)	4.00	(0.78,107.87) (0.59,26.92)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.1.17 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		24	15	62.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.17 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.18 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	33	18	54.5	(38.0, 70.2)	0.0026	43.4	(9.4,64.3)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	8	61.5	(35.5, 82.3)	0.1640	61.5	(-11.8,87.6)
Female	15	2	13.3	(3.7, 37.9)	20	10	50.0	(29.9, 70.1)	0.0252	36.7	(4.4,63.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	10	5	50.0	(23.7, 76.3)	0.5457	25.0	(-37.9,68.5)
< 50 years	14	1	7.1	(1.3, 31.5)	23	13	56.5	(36.8, 74.4)	0.0029	49.4	(12.1,71.6)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	10	62.5	(38.6, 81.5)	0.0115	47.1	(10.7,74.8)
White	5	0	0.0	(0.0, 43.4)	17	8	47.1	(26.2, 69.0)	0.0995	47.1	(-8.9,72.7)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	9	64.3	(38.8, 83.7)	0.0112	48.9	(9.3,77.9)
BMI											
< 25 kg/m2	9	0	0.0		13	8	61.5				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		22	10	45.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.1.18 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.60	(2.01,67.41)	4.91	(1.35,55.31) (1.28,18.81)	
Sex					NC
Male	inf	(1.00, inf)	inf	(0.85, inf)	
Female	6.50	(1.18,49.39)	3.75	(1.05,40.61) (0.96,14.65)	
Age					0.3069
>= 50 years	3.00	(0.21,93.71)	2.00	(0.44,53.18) (0.33,12.18)	
< 50 years	16.90	(2.20,387.70)	7.91	(1.41,226.40) (1.16,54.10)	
Race					NC
Asian	9.17	(1.47,72.54)	4.06	(1.23,43.94) (1.07,15.36)	
White	inf	(1.17, inf)	inf	(0.81, inf)	
Region					NC
Europe + Africa + US	inf	(1.22, inf)	inf	(0.84, inf)	
Asia(ex Japan) + Japan	9.90	(1.50,80.39)	4.18	(1.22,30.59) (1.10,15.85)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.18 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	1	9.1	(1.6, 37.7)	19	9	47.4	(27.3, 68.3)	0.0547	38.3	(-0.6,64.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	21	13	61.9	(40.9, 79.2)	0.0050	53.6	(14.7,76.3)
=4	6	1	16.7	(3.0, 56.4)	12	5	41.7	(19.3, 68.0)	0.4438	25.0	(-28.1,62.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	26	16	61.5	(42.5, 77.6)	0.0032	48.2	(11.4,70.5)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		27	14	51.9				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	14	6	42.9	(21.4, 67.4)	0.0426	42.9	(1.3,71.1)
No	10	2	20.0	(5.7, 51.0)	19	12	63.2	(41.0, 80.9)	0.0394	43.2	(1.5,71.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		32	17	53.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		30	16	53.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.18 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.8102
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	9.00	(1.08,217.16)	5.21	(0.99,142.15) (0.76,35.82)	
Baseline GPPGA pustulation subscore					0.4290
<4	17.88	(2.19,414.84)	7.43	(1.38,215.14) (1.10,49.98)	
=4	3.57	(0.32,100.84)	2.50	(0.50,65.50) (0.37,16.89)	
Baseline GPPGA score					NC
=3	10.40	(1.99,75.70)	4.62	(1.27,44.52) (1.23,17.37)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.60, inf)	inf	(1.02, inf)	
No	6.86	(1.11,54.80)	3.16	(1.02,28.50) (0.87,11.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.4.1.18 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		24	14	58.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.18 Proportion of patients with DLQI symptoms and feelings score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI symptoms and feelings score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.19 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	15	5	33.3	(15.2, 58.3)	27	15	55.6	(37.3, 72.4)	0.1857	22.2	(-10.5,50.6)
Sex											
Male	2	0	0.0	(0.0, 65.8)	10	7	70.0	(39.7, 89.2)	0.1459	70.0	(-15.6,93.3)
Female	13	5	38.5	(17.7, 64.5)	17	8	47.1	(26.2, 69.0)	0.6845	8.6	(-27.9,43.1)
Age											
>= 50 years	3	1	33.3	(6.1, 79.2)	7	3	42.9	(15.8, 75.0)	0.9428	9.5	(-58.8,65.2)
< 50 years	12	4	33.3	(13.8, 60.9)	20	12	60.0	(38.7, 78.1)	0.1712	26.7	(-10.8,58.2)
Race											
Asian	11	4	36.4	(15.2, 64.6)	14	7	50.0	(26.8, 73.2)	0.6270	13.6	(-26.6,50.8)
White	4	1	25.0	(4.6, 69.9)	13	8	61.5	(35.5, 82.3)	0.2679	36.5	(-22.9,75.8)
Region											
Europe + Africa + US	4	1	25.0	(4.6, 69.9)	15	9	60.0	(35.7, 80.2)	0.2722	35.0	(-23.5,72.9)
Asia(ex Japan) + Japan	11	4	36.4	(15.2, 64.6)	12	6	50.0	(25.4, 74.6)	0.6247	13.6	(-28.4,53.8)
BMI											
< 25 kg/m2	8	4	50.0		8	5	62.5				
25 to < 30 kg/m2	4	0	0.0		9	3	33.3				
>= 30 kg/m2	3	1	33.3		10	7	70.0				
Mutation status IL36RN											
Yes	1	0	0.0		4	4	100.0				
No	10	4	40.0		19	8	42.1				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.19 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.50	(0.66,9.92)	1.67	(0.80,8.03) (0.76,3.68)	
Sex					NC
Male	inf	(0.72, inf)	inf	(0.73, inf)	
Female	1.42	(0.31,6.59)	1.22	(0.50,3.48) (0.52,2.87)	
Age					0.7435
>= 50 years	1.50	(0.07,58.21)	1.29	(0.23,33.89) (0.21,7.89)	
< 50 years	3.00	(0.65,14.53)	1.80	(0.81,8.75) (0.75,4.32)	
Race					0.5658
Asian	1.75	(0.33,9.58)	1.38	(0.54,4.91) (0.54,3.52)	
White	4.80	(0.36,140.81)	2.46	(0.64,68.75) (0.43,14.18)	
Region					0.5844
Europe + Africa + US	4.50	(0.36,130.53)	2.40	(0.64,67.34) (0.42,13.77)	
Asia(ex Japan) + Japan	1.75	(0.31,10.11)	1.38	(0.50,4.92) (0.52,3.61)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.1.19 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	0	0.0	(0.0, 43.4)	6	5	83.3	(43.6, 97.0)	0.0070	83.3	(23.7,99.6)
No	9	4	44.4	(18.9, 73.3)	17	7	41.2	(21.6, 64.0)	0.9381	-3.3	(-43.0,35.9)
Baseline GPPGA pustulation subscore											
<4	11	5	45.5	(21.3, 72.0)	16	9	56.3	(33.2, 76.9)	0.6922	10.8	(-28.0,47.3)
=4	4	0	0.0	(0.0, 49.0)	11	6	54.5	(28.0, 78.7)	0.0794	54.5	(-10.7,83.3)
Baseline GPPGA score											
=3	13	5	38.5		21	13	61.9				
=4	2	0	0.0		6	2	33.3				
Baseline plaque psoriasis											
Yes	3	1	33.3		5	4	80.0				
No	12	4	33.3		22	11	50.0				
Background treatment prior to randomization											
Yes	6	2	33.3	(9.7, 70.0)	10	6	60.0	(31.3, 83.2)	0.4303	26.7	(-26.3,69.1)
No	9	3	33.3	(12.1, 64.6)	17	9	52.9	(31.0, 73.8)	0.4297	19.6	(-22.4,55.2)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	14	5	35.7		27	15	55.6				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	15	5	33.3		25	14	56.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.19 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					NC
Yes	inf	(2.97, inf)	inf	(1.62, inf)	
No	0.88	(0.16,4.93)	0.93	(0.36,3.33) (0.37,2.34)	
Baseline GPPGA pustulation subscore					NC
<4	1.54	(0.31,7.69)	1.24	(0.57,3.75) (0.57,2.70)	
=4	inf	(1.05, inf)	inf	(0.83, inf)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8789
Yes	3.00	(0.33,31.20)	1.80	(0.55,19.53) (0.52,6.22)	
No	2.25	(0.40,13.90)	1.59	(0.62,7.73) (0.57,4.43)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.19 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	14	4	28.6		20	12	60.0			
Mild	1	1	100.0		5	1	20.0			
Moderate	0	0	na		1	1	100.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.19 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.20 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	15	1	6.7	(1.2, 29.8)	27	13	48.1	(30.7, 66.0)	0.0079	41.5	(6.8,63.0)
Sex											
Male	2	0	0.0		10	5	50.0				
Female	13	1	7.7		17	8	47.1				
Age											
>= 50 years	3	1	33.3	(6.1, 79.2)	7	2	28.6	(8.2, 64.1)	1.0000	-4.8	(-70.8,53.0)
< 50 years	12	0	0.0	(0.0, 24.2)	20	11	55.0	(34.2, 74.2)	0.0017	55.0	(20.9,76.9)
Race											
Asian	11	1	9.1		14	7	50.0				
White	4	0	0.0		13	6	46.2				
Region											
Europe + Africa + US	4	0	0.0		15	7	46.7				
Asia(ex Japan) + Japan	11	1	9.1		12	6	50.0				
BMI											
< 25 kg/m2	8	0	0.0		8	3	37.5				
25 to < 30 kg/m2	4	1	25.0		9	4	44.4				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	1	0	0.0		4	4	100.0				
No	10	0	0.0		19	7	36.8				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.1.20 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	13.00	(1.79,297.08)	7.22	(1.13,203.25) (1.04,49.93)	
Sex					
Male					
Female					
Age					NC
>= 50 years	0.80	(0.04,34.87)	0.86	(0.10,23.16) (0.12,6.23)	
< 50 years	inf	(4.42, inf)	inf	(1.75, inf)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.20 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	5	1	20.0		6	4	66.7				
No	9	0	0.0		17	7	41.2				
Baseline GPPGA pustulation subscore											
<4	11	1	9.1	(1.6, 37.7)	16	9	56.3	(33.2, 76.9)	0.0148	47.2	(8.0,74.0)
=4	4	0	0.0	(0.0, 49.0)	11	4	36.4	(15.2, 64.6)	0.2581	36.4	(-26.6,69.2)
Baseline GPPGA score											
=3	13	1	7.7		21	12	57.1				
=4	2	0	0.0		6	1	16.7				
Baseline plaque psoriasis											
Yes	3	0	0.0		5	3	60.0				
No	12	1	8.3		22	10	45.5				
Background treatment prior to randomization											
Yes	6	0	0.0	(0.0, 39.0)	10	4	40.0	(16.8, 68.7)	0.1402	40.0	(-10.6,73.8)
No	9	1	11.1	(2.0, 43.5)	17	9	52.9	(31.0, 73.8)	0.0417	41.8	(1.5,70.0)
Pain VAS score at baseline											
<= 40	1	0	0.0		0	0	na				
> 40	14	1	7.1		27	13	48.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	15	1	6.7		25	12	48.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.20 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	12.86	(1.45,309.80)	6.19	(1.16,171.81) (0.91,42.12)	
=4	inf	(0.50, inf)	inf	(0.46, inf)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(0.91, inf)	inf	(0.70, inf)	
No	9.00	(1.01,221.73)	4.76	(0.97,131.42) (0.71,31.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.20 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	14	1	7.1		20	11	55.0			
Mild	1	0	0.0		5	1	20.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.20 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.21 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	15	1	6.7	(1.2, 29.8)	27	13	48.1	(30.7, 66.0)	0.0079	41.5	(6.8,63.0)
Sex											
Male	2	0	0.0		10	6	60.0				
Female	13	1	7.7		17	7	41.2				
Age											
>= 50 years	3	1	33.3	(6.1, 79.2)	7	2	28.6	(8.2, 64.1)	1.0000	-4.8	(-70.8,53.0)
< 50 years	12	0	0.0	(0.0, 24.2)	20	11	55.0	(34.2, 74.2)	0.0017	55.0	(20.9,76.9)
Race											
Asian	11	1	9.1		14	8	57.1				
White	4	0	0.0		13	5	38.5				
Region											
Europe + Africa + US	4	0	0.0		15	6	40.0				
Asia(ex Japan) + Japan	11	1	9.1		12	7	58.3				
BMI											
< 25 kg/m2	8	0	0.0		8	3	37.5				
25 to < 30 kg/m2	4	1	25.0		9	5	55.6				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	1	0	0.0		4	3	75.0				
No	10	0	0.0		19	8	42.1				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.21 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	13.00	(1.79,297.08)	7.22	(1.13,203.25) (1.04,49.93)	
Sex					
Male					
Female					
Age					NC
>= 50 years	0.80	(0.04,34.87)	0.86	(0.10,23.16) (0.12,6.23)	
< 50 years	inf	(4.42, inf)	inf	(1.75, inf)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.21 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	5	1	20.0		6	3	50.0			
No	9	0	0.0		17	8	47.1			
Baseline GPPGA pustulation subscore										
<4	11	1	9.1		16	8	50.0			
=4	4	0	0.0		11	5	45.5			
Baseline GPPGA score										
=3	13	1	7.7		21	11	52.4			
=4	2	0	0.0		6	2	33.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		5	4	80.0			
No	12	1	8.3		22	9	40.9			
Background treatment prior to randomization										
Yes	6	0	0.0	(0.0, 39.0)	10	3	30.0	(10.8, 60.3)	0.1832	30.0 (-16.7,65.2)
No	9	1	11.1	(2.0, 43.5)	17	10	58.8	(36.0, 78.4)	0.0374	47.7 (2.0,74.8)
Pain VAS score at baseline										
<= 40	1	0	0.0		0	0	na			
> 40	14	1	7.1		27	13	48.1			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	15	1	6.7		25	12	48.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.1.21 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(0.56, inf)	inf	(0.50, inf)	
No	11.43	(1.27,278.69)	5.29	(1.06,149.07) (0.80,35.05)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.21 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	14	1	7.1		20	11	55.0			
Mild	1	0	0.0		5	1	20.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.1.21 Proportion of patients with DLQI treatment score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI treatment score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.22 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	13	5	38.5	(17.7, 64.5)	23	2	8.7	(2.4, 26.8)	0.0555	-29.8 (-59.9,0.6)
Sex										
Male	3	1	33.3		9	1	11.1			
Female	10	4	40.0		14	1	7.1			
Age										
>= 50 years	2	1	50.0		8	2	25.0			
< 50 years	11	4	36.4		15	0	0.0			
Race										
Asian	9	3	33.3		13	1	7.7			
White	4	2	50.0		10	1	10.0			
Region										
Europe + Africa + US	4	2	50.0		11	1	9.1			
Asia(ex Japan) + Japan	9	3	33.3		12	1	8.3			
BMI										
< 25 kg/m2	5	2	40.0		8	1	12.5			
25 to < 30 kg/m2	6	3	50.0		7	0	0.0			
>= 30 kg/m2	2	0	0.0		8	1	12.5			
Mutation status IL36RN										
Yes	2	1	50.0		3	1	33.3			
No	8	4	50.0		16	1	6.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.22 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.15	(0.02,0.99)	0.23	(0.03,1.03) (0.05,1.01)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.22 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	4	2	50.0		6	2	33.3			
No	8	3	37.5		13	0	0.0			
Baseline GPPGA pustulation subscore										
<4	7	2	28.6		13	1	7.7			
=4	6	3	50.0		10	1	10.0			
Baseline GPPGA score										
=3	10	3	30.0		16	1	6.3			
=4	3	2	66.7		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		5	0	0.0			
No	10	5	50.0		18	2	11.1			
Background treatment prior to randomization										
Yes	6	2	33.3		9	0	0.0			
No	7	3	42.9		14	2	14.3			
Pain VAS score at baseline										
<= 40	1	1	100.0		0	0	na			
> 40	12	4	33.3		23	2	8.7			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	13	5	38.5		22	2	9.1			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.22 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.22 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	12	4	33.3		16	1	6.3			
Mild	0	0	na		5	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.22 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 1 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.23 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	13	2	15.4	(4.3, 42.2)	23	10	43.5	(25.6, 63.2)	0.1345	28.1 (-6.4,54.3)
Sex										
Male	3	0	0.0		9	3	33.3			
Female	10	2	20.0		14	7	50.0			
Age										
>= 50 years	2	0	0.0		8	3	37.5			
< 50 years	11	2	18.2		15	7	46.7			
Race										
Asian	9	2	22.2		13	5	38.5			
White	4	0	0.0		10	5	50.0			
Region										
Europe + Africa + US	4	0	0.0		11	5	45.5			
Asia(ex Japan) + Japan	9	2	22.2		12	5	41.7			
BMI										
< 25 kg/m2	5	1	20.0		8	4	50.0			
25 to < 30 kg/m2	6	1	16.7		7	1	14.3			
>= 30 kg/m2	2	0	0.0		8	5	62.5			
Mutation status IL36RN										
Yes	2	0	0.0		3	3	100.0			
No	8	2	25.0		16	5	31.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.23 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.23	(0.78,32.41)	2.83	(0.84,30.62) (0.73,10.98)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.23 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	4	0	0.0		6	4	66.7			
No	8	2	25.0		13	4	30.8			
Baseline GPPGA pustulation subscore										
<4	7	0	0.0		13	6	46.2			
=4	6	2	33.3		10	4	40.0			
Baseline GPPGA score										
=3	10	2	20.0	(5.7, 51.0)	16	9	56.3	(33.2, 76.9)	0.1072	36.3 (-4.5,67.0)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3 (-54.0,58.9)
Baseline plaque psoriasis										
Yes	3	0	0.0		5	2	40.0			
No	10	2	20.0		18	8	44.4			
Background treatment prior to randomization										
Yes	6	1	16.7		9	3	33.3			
No	7	1	14.3		14	7	50.0			
Pain VAS score at baseline										
<= 40	1	0	0.0		0	0	na			
> 40	12	2	16.7		23	10	43.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	13	2	15.4		22	9	40.9			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.23 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	5.14	(0.81,42.41)	2.81	(0.87,20.92) (0.76,10.45)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.23 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	12	2	16.7		16	8	50.0			
Mild	0	0	na		5	1	20.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.23 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 4 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.24 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	13	1	7.7	(1.4, 33.3)	23	11	47.8	(29.2, 67.0)	0.0184	40.1 (5.4,63.7)
Sex										
Male	3	0	0.0		9	4	44.4			
Female	10	1	10.0		14	7	50.0			
Age										
>= 50 years	2	0	0.0		8	3	37.5			
< 50 years	11	1	9.1		15	8	53.3			
Race										
Asian	9	1	11.1		13	6	46.2			
White	4	0	0.0		10	5	50.0			
Region										
Europe + Africa + US	4	0	0.0		11	5	45.5			
Asia(ex Japan) + Japan	9	1	11.1		12	6	50.0			
BMI										
< 25 kg/m2	5	0	0.0		8	4	50.0			
25 to < 30 kg/m2	6	1	16.7		7	2	28.6			
>= 30 kg/m2	2	0	0.0		8	5	62.5			
Mutation status IL36RN										
Yes	2	0	0.0		3	3	100.0			
No	8	1	12.5		16	6	37.5			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.24 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	11.00	(1.43,257.11)	6.22	(1.09,172.42) (0.90,42.87)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.24 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	4	0	0.0		6	4	66.7			
No	8	1	12.5		13	5	38.5			
Baseline GPPGA pustulation subscore										
<4	7	0	0.0		13	6	46.2			
=4	6	1	16.7		10	5	50.0			
Baseline GPPGA score										
=3	10	1	10.0	(1.8, 40.4)	16	9	56.3	(33.2, 76.9)	0.0227	46.3 (6.4,73.7)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6 (-41.8,71.0)
Baseline plaque psoriasis										
Yes	3	0	0.0		5	3	60.0			
No	10	1	10.0		18	8	44.4			
Background treatment prior to randomization										
Yes	6	0	0.0		9	3	33.3			
No	7	1	14.3		14	8	57.1			
Pain VAS score at baseline										
<= 40	1	0	0.0		0	0	na			
> 40	12	1	8.3		23	11	47.8			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	13	1	7.7		22	10	45.5			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.24 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	11.57	(1.29,281.53)	5.63	(1.09,156.21) (0.83,37.95)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.24 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	12	1	8.3		16	9	56.3			
Mild	0	0	na		5	1	20.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.1.24 Proportion of patients with DLQI work and school score improvement of at least 1 from baseline overall and by subgroup at week 12 - RS, patients with DLQI work and school score >= 1 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.3.4.2 DLQI score of 0 or 1

Table 2.3.4.2.1 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 1 – RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	(0.0, 17.6)	35	2	5.7	(1.6, 18.6)	0.4283	5.7	(-13.7,19.5)
Sex											
Male	3	0	0.0		14	2	14.3				
Female	15	0	0.0		21	0	0.0				
Age											
>= 50 years	4	0	0.0		11	1	9.1				
< 50 years	14	0	0.0		24	1	4.2				
Race											
Asian	13	0	0.0		16	0	0.0				
White	5	0	0.0		19	2	10.5				
Region											
Europe + Africa + US	5	0	0.0		21	2	9.5				
Asia(ex Japan) + Japan	13	0	0.0		14	0	0.0				
BMI											
< 25 kg/m2	9	0	0.0		15	1	6.7				
25 to < 30 kg/m2	6	0	0.0		10	1	10.0				
>= 30 kg/m2	3	0	0.0		10	0	0.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	0	0.0				
No	12	0	0.0		24	2	8.3				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.1 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 1 – RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.1 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	0	0.0			
No	11	0	0.0		21	2	9.5			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	2	9.1			
=4	6	0	0.0		13	0	0.0			
Baseline GPPGA score										
=3	15	0	0.0		28	2	7.1			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	0	0.0			
No	15	0	0.0		29	2	6.9			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	0	0.0		20	1	5.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	0	0.0		34	2	5.9			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	0	0.0		32	2	6.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.1 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.1 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	0	0.0		26	2	7.7			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.1 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.2 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	8	22.9	(12.1, 39.0)	0.1336	17.3	(-7.8,36.0)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	1	6.7		21	4	19.0				
Age											
>= 50 years	4	0	0.0		11	2	18.2				
< 50 years	14	1	7.1		24	6	25.0				
Race											
Asian	13	1	7.7		16	2	12.5				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	6	28.6				
Asia(ex Japan) + Japan	13	1	7.7		14	2	14.3				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	1	16.7		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	4	16.7				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.2 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.04	(0.70,118.83)	4.11	(0.72,107.24) (0.56,30.39)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.2 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	3	37.5			
No	11	1	9.1		21	4	19.0			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	7	31.8			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	8	28.6			
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	7	24.1			
Background treatment prior to randomization										
Yes	8	0	0.0		15	1	6.7			
No	10	1	10.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	1	6.3		34	7	20.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	8	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.2 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.2 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	6	23.1			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.2 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.3 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	11	31.4	(18.6, 48.0)	0.0477	25.9 (0.2,44.8)
Sex										
Male	3	0	0.0		14	5	35.7			
Female	15	1	6.7		21	6	28.6			
Age										
>= 50 years	4	0	0.0		11	3	27.3			
< 50 years	14	1	7.1		24	8	33.3			
Race										
Asian	13	1	7.7		16	5	31.3			
White	5	0	0.0		19	6	31.6			
Region										
Europe + Africa + US	5	0	0.0		21	7	33.3			
Asia(ex Japan) + Japan	13	1	7.7		14	4	28.6			
BMI										
< 25 kg/m2	9	0	0.0		15	6	40.0			
25 to < 30 kg/m2	6	1	16.7		10	2	20.0			
>= 30 kg/m2	3	0	0.0		10	3	30.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	3	60.0			
No	12	1	8.3		24	7	29.2			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.3 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	7.79	(1.13,178.44)	5.66	(1.00,152.72) (0.79,40.43)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.3 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	4	50.0			
No	11	1	9.1		21	6	28.6			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0	(0.0, 24.2)	22	10	45.5	(26.9, 65.3)	0.0065	45.5 (13.3,67.8)
=4	6	1	16.7	(3.0, 56.4)	13	1	7.7	(1.4, 33.3)	0.8189	-9.0 (-54.7,25.5)
Baseline GPPGA score										
=3	15	1	6.7	(1.2, 29.8)	28	11	39.3	(23.6, 57.6)	0.0266	32.6 (2.5,55.1)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	10	34.5			
Background treatment prior to randomization										
Yes	8	0	0.0		15	4	26.7			
No	10	1	10.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	1	6.3		34	10	29.4			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	11	34.4			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.3 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(3.11, inf)	inf	(1.27, inf)	
=4	0.42	(0.01,19.39)	0.46	(0.01,15.12) (0.03,6.20)	
Baseline GPPGA score					NC
=3	9.06	(1.25,209.69)	5.89	(1.03,161.02) (0.84,41.36)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.3 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	8	30.8			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.3 Proportion of patients with DLQI score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.4 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	10	28.6	(16.3, 45.1)	0.4283	11.9 (-15.5,33.7)
Sex										
Male	3	0	0.0		14	4	28.6			
Female	15	3	20.0		21	6	28.6			
Age										
>= 50 years	4	1	25.0		11	4	36.4			
< 50 years	14	2	14.3		24	6	25.0			
Race										
Asian	13	3	23.1		16	3	18.8			
White	5	0	0.0		19	7	36.8			
Region										
Europe + Africa + US	5	0	0.0		21	7	33.3			
Asia(ex Japan) + Japan	13	3	23.1		14	3	21.4			
BMI										
< 25 kg/m2	9	2	22.2		15	6	40.0			
25 to < 30 kg/m2	6	1	16.7		10	1	10.0			
>= 30 kg/m2	3	0	0.0		10	3	30.0			
Mutation status IL36RN										
Yes	2	0	0.0		5	0	0.0			
No	12	2	16.7		24	7	29.2			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.4 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.00	(0.48,10.17)	1.71	(0.58,7.65) (0.54,5.46)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.4 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 1 – RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	2	25.0			
No	11	2	18.2		21	5	23.8			
Baseline GPPGA pustulation subscore										
<4	12	2	16.7		22	7	31.8			
=4	6	1	16.7		13	3	23.1			
Baseline GPPGA score										
=3	15	3	20.0	(7.0, 45.2)	28	9	32.1	(17.9, 50.7)	0.4499	12.1 (-19.2,37.5)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3 (-54.0,58.9)
Baseline plaque psoriasis										
Yes	3	1	33.3		6	0	0.0			
No	15	2	13.3		29	10	34.5			
Background treatment prior to randomization										
Yes	8	0	0.0		15	5	33.3			
No	10	3	30.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	1	50.0		1	0	0.0			
> 40	16	2	12.5		34	10	29.4			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	3	16.7		32	8	25.0			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.4 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 1 – RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	1.89	(0.43,10.07)	1.61	(0.54,7.92) (0.51,5.06)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.4 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 1 – RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	8	30.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.4 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.5 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	14	40.0	(25.6, 56.4)	0.0476	28.9	(0.2,49.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	2	13.3	(3.7, 37.9)	21	8	38.1	(20.8, 59.1)	0.1384	24.8	(-6.9,51.7)
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	5	45.5	(21.3, 72.0)	0.2581	45.5	(-15.3,76.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	9	37.5	(21.2, 57.3)	0.1663	23.2	(-8.9,48.9)
Race											
Asian	13	2	15.4		16	7	43.8				
White	5	0	0.0		19	7	36.8				
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	2	15.4		14	6	42.9				
BMI											
< 25 kg/m2	9	1	11.1		15	8	53.3				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	3	30.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	2	16.7		24	8	33.3				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.5 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.33	(1.13,37.92)	3.60	(1.00,39.66) (0.92,14.14)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	4.00	(0.72,31.00)	2.86	(0.77,23.60) (0.70,11.59)	
Age					NC
>= 50 years	inf	(0.74, inf)	inf	(0.64, inf)	
< 50 years	3.60	(0.67,27.59)	2.63	(0.74,22.92) (0.66,10.47)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.5 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	5	62.5			
No	11	2	18.2		21	6	28.6			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0	(0.0, 24.2)	22	12	54.5	(34.7, 73.1)	0.0016	54.5 (21.1,75.6)
=4	6	2	33.3	(9.7, 70.0)	13	2	15.4	(4.3, 42.2)	0.4859	-17.9 (-64.2,23.8)
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	13	46.4	(29.5, 64.2)	0.0504	33.1 (0.0,56.4)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3 (-54.0,58.9)
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	13	44.8			
Background treatment prior to randomization										
Yes	8	1	12.5	(2.2, 47.1)	15	5	33.3	(15.2, 58.3)	0.3866	20.8 (-24.2,52.9)
No	10	1	10.0	(1.8, 40.4)	20	9	45.0	(25.8, 65.8)	0.0791	35.0 (-5.0,61.9)
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	2	12.5		34	13	38.2			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	13	40.6			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.5 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.44, inf)	inf	(1.75, inf)	
=4	0.36	(0.03,4.76)	0.46	(0.03,6.63) (0.08,2.54)	
Baseline GPPGA score					NC
=3	5.63	(1.12,41.24)	3.48	(1.00,37.27) (0.90,13.43)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7093
Yes	3.50	(0.36,94.38)	2.67	(0.49,69.03) (0.37,19.09)	
No	7.36	(0.89,179.46)	4.50	(0.86,122.26) (0.66,30.74)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.5 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	10	38.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.5 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.6 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	15	42.9	(28.0, 59.1)	0.0235	31.7	(2.2,52.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	2	13.3	(3.7, 37.9)	21	9	42.9	(24.5, 63.5)	0.0727	29.5	(-2.6,56.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	10	41.7	(24.5, 61.2)	0.0301	34.5	(2.1,58.1)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	8	50.0	(28.0, 72.0)	0.0742	34.6	(-3.1,64.7)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	2	15.4		14	7	50.0				
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	9	37.5				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.6 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.00	(1.27,42.46)	3.86	(1.02,39.66) (0.99,15.05)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	4.88	(0.89,37.29)	3.21	(0.92,27.20) (0.81,12.80)	
Age					0.3909
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	9.29	(1.23,217.63)	5.83	(1.02,158.80) (0.83,40.88)	
Race					NC
Asian	5.50	(0.91,44.05)	3.25	(0.95,26.73) (0.83,12.74)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.6 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	5	62.5				
No	11	1	9.1		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	1	16.7	(3.0, 56.4)	13	2	15.4	(4.3, 42.2)	1.0000	-1.3	(-47.5,34.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	14	50.0	(32.6, 67.4)	0.0250	36.7	(2.5,59.7)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	1	16.7				
No	15	2	13.3		29	14	48.3				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	9	45.0	(25.8, 65.8)	0.3035	25.0	(-14.9,55.6)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	14	41.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	14	43.8				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.6 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.1697
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	0.91	(0.06,31.93)	0.92	(0.09,24.95) (0.10,8.31)	
Baseline GPPGA score					NC
=3	6.50	(1.29,47.35)	3.75	(1.06,41.33) (0.98,14.35)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	3.27	(0.55,26.49)	2.25	(0.69,17.96) (0.59,8.52)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.6 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	11	42.3			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.6 Proportion of patients with DLQI daily activities score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.7 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 1 – RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	4	22.2	(9.0, 45.2)	35	8	22.9	(12.1, 39.0)	1.0000	0.6	(-26.5,23.4)
Sex											
Male	3	0	0.0		14	6	42.9				
Female	15	4	26.7		21	2	9.5				
Age											
>= 50 years	4	1	25.0		11	2	18.2				
< 50 years	14	3	21.4		24	6	25.0				
Race											
Asian	13	3	23.1		16	1	6.3				
White	5	1	20.0		19	7	36.8				
Region											
Europe + Africa + US	5	1	20.0		21	7	33.3				
Asia(ex Japan) + Japan	13	3	23.1		14	1	7.1				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	3	50.0		10	2	20.0				
>= 30 kg/m2	3	1	33.3		10	2	20.0				
Mutation status IL36RN											
Yes	2	1	50.0		5	0	0.0				
No	12	3	25.0		24	6	25.0				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.7 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.04	(0.26,4.56)	1.03	(0.35,5.62) (0.36,2.96)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.7 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	2	33.3		8	0	0.0			
No	11	2	18.2		21	6	28.6			
Baseline GPPGA pustulation subscore										
<4	12	2	16.7		22	5	22.7			
=4	6	2	33.3		13	3	23.1			
Baseline GPPGA score										
=3	15	3	20.0	(7.0, 45.2)	28	7	25.0	(12.7, 43.4)	0.8419	5.0 (-24.9,30.0)
=4	3	1	33.3	(6.1, 79.2)	7	1	14.3	(2.6, 51.3)	0.8467	-19.0 (-79.3,39.0)
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	4	26.7		29	7	24.1			
Background treatment prior to randomization										
Yes	8	1	12.5		15	4	26.7			
No	10	3	30.0		20	4	20.0			
Pain VAS score at baseline										
<= 40	2	1	50.0		1	1	100.0			
> 40	16	3	18.8		34	7	20.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	4	22.2		32	7	21.9			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.7 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					0.4371
=3	1.33	(0.29,7.35)	1.25	(0.37,7.88) (0.38,4.14)	
=4	0.33	(0.01,19.29)	0.43	(0.01,13.81) (0.04,4.82)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.7 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	7	26.9			
Mild	1	0	0.0		6	0	0.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.7 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.8 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	12	34.3	(20.8, 50.8)	0.0845	23.2	(-3.8,43.8)
Sex											
Male	3	0	0.0		14	5	35.7				
Female	15	2	13.3		21	7	33.3				
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	4	36.4	(15.2, 64.6)	0.2581	36.4	(-26.6,69.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	8	33.3	(18.0, 53.3)	0.3430	19.0	(-12.5,44.9)
Race											
Asian	13	2	15.4		16	4	25.0				
White	5	0	0.0		19	8	42.1				
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	2	15.4		14	4	28.6				
BMI											
< 25 kg/m2	9	1	11.1		15	7	46.7				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	2	20.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	2	16.7		24	6	25.0				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.8 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.17	(0.87,30.05)	3.09	(0.87,27.91) (0.77,12.32)	
Sex					
Male					
Female					
Age					NC
>= 50 years	inf	(0.50, inf)	inf	(0.46, inf)	
< 50 years	3.00	(0.55,23.31)	2.33	(0.66,19.31) (0.57,9.48)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.8 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0		8	4	50.0				
No	11	2	18.2		21	5	23.8				
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	10	45.5	(26.9, 65.3)	0.0065	45.5	(13.3,67.8)
=4	6	2	33.3	(9.7, 70.0)	13	2	15.4	(4.3, 42.2)	0.4859	-17.9	(-64.2,23.8)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	12	42.9	(26.5, 60.9)	0.0874	29.5	(-2.0,53.0)
=4	3	0	0.0		7	0	0.0				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	1	16.7				
No	15	2	13.3		29	11	37.9				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	3	20.0	(7.0, 45.2)	0.8258	7.5	(-32.7,39.5)
No	10	1	10.0	(1.8, 40.4)	20	9	45.0	(25.8, 65.8)	0.0791	35.0	(-5.0,61.9)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	11	32.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	11	34.4				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.8 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(3.11, inf)	inf	(1.27, inf)	
=4	0.36	(0.03,4.76)	0.46	(0.03,6.63) (0.08,2.54)	
Baseline GPPGA score					NC
=3	4.88	(0.96,35.90)	3.21	(0.94,29.05) (0.83,12.51)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.4758
Yes	1.75	(0.15,52.28)	1.60	(0.19,41.31) (0.20,12.99)	
No	7.36	(0.89,179.46)	4.50	(0.86,122.26) (0.66,30.74)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.8 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	9	34.6			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.8 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.9 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	14	40.0	(25.6, 56.4)	0.0162	34.4	(5.8,53.9)
Sex											
Male	3	0	0.0		14	6	42.9				
Female	15	1	6.7		21	8	38.1				
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	5	45.5	(21.3, 72.0)	0.2581	45.5	(-15.3,76.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	9	37.5	(21.2, 57.3)	0.0631	30.4	(-1.3,53.9)
Race											
Asian	13	1	7.7		16	6	37.5				
White	5	0	0.0		19	8	42.1				
Region											
Europe + Africa + US	5	0	0.0		21	9	42.9				
Asia(ex Japan) + Japan	13	1	7.7		14	5	35.7				
BMI											
< 25 kg/m2	9	0	0.0		15	7	46.7				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	7	29.2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.9 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	11.33	(1.67,255.05)	7.20	(1.11,201.10) (1.03,50.48)	
Sex					
Male					
Female					
Age					NC
>= 50 years	inf	(0.74, inf)	inf	(0.64, inf)	
< 50 years	7.80	(1.02,184.62)	5.25	(0.98,140.82) (0.74,37.20)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.9 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0		8	5	62.5				
No	11	1	9.1		21	6	28.6				
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	12	54.5	(34.7, 73.1)	0.0016	54.5	(21.1,75.6)
=4	6	1	16.7	(3.0, 56.4)	13	2	15.4	(4.3, 42.2)	1.0000	-1.3	(-47.5,34.4)
Baseline GPPGA score											
=3	15	1	6.7	(1.2, 29.8)	28	14	50.0	(32.6, 67.4)	0.0070	43.3	(11.6,64.3)
=4	3	0	0.0		7	0	0.0				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	1	6.7		29	12	41.4				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	5	33.3	(15.2, 58.3)	0.1229	33.3	(-6.9,61.6)
No	10	1	10.0	(1.8, 40.4)	20	9	45.0	(25.8, 65.8)	0.0791	35.0	(-5.0,61.9)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	1	6.3		34	13	38.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	1	5.6		32	13	40.6				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.9 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.44, inf)	inf	(1.75, inf)	
=4	0.91	(0.06,31.93)	0.92	(0.09,24.95) (0.10,8.31)	
Baseline GPPGA score					NC
=3	14.00	(1.94,318.36)	7.50	(1.13,213.18) (1.09,51.64)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.07, inf)	inf	(0.81, inf)	
No	7.36	(0.89,179.46)	4.50	(0.86,122.26) (0.66,30.74)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.9 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	10	38.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.9 Proportion of patients with DLQI leisure score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.10 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	9	50.0	(29.0, 71.0)	35	18	51.4	(35.6, 67.0)	0.9735	1.4	(-27.1,30.0)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	9	60.0	(35.7, 80.2)	21	11	52.4	(32.4, 71.7)	0.7226	-7.6	(-39.5,27.6)
Age											
>= 50 years	4	4	100.0	(51.0, 100.0)	11	6	54.5	(28.0, 78.7)	0.2581	-45.5	(-76.6,15.3)
< 50 years	14	5	35.7	(16.3, 61.2)	24	12	50.0	(31.4, 68.6)	0.4380	14.3	(-19.5,44.9)
Race											
Asian	13	8	61.5	(35.5, 82.3)	16	9	56.3	(33.2, 76.9)	0.8275	-5.3	(-41.0,31.3)
White	5	1	20.0	(3.6, 62.4)	19	9	47.4	(27.3, 68.3)	0.3749	27.4	(-26.5,61.3)
Region											
Europe + Africa + US	5	1	20.0	(3.6, 62.4)	21	10	47.6	(28.3, 67.6)	0.3830	27.6	(-26.3,60.3)
Asia(ex Japan) + Japan	13	8	61.5	(35.5, 82.3)	14	8	57.1	(32.6, 78.6)	0.9172	-4.4	(-42.8,33.4)
BMI											
< 25 kg/m2	9	3	33.3	(12.1, 64.6)	15	10	66.7	(41.7, 84.8)	0.1604	33.3	(-9.8,67.8)
25 to < 30 kg/m2	6	4	66.7	(30.0, 90.3)	10	4	40.0	(16.8, 68.7)	0.4303	-26.7	(-69.1,26.3)
>= 30 kg/m2	3	2	66.7	(20.8, 93.9)	10	4	40.0	(16.8, 68.7)	0.6571	-26.7	(-75.2,40.6)
Mutation status IL36RN											
Yes	2	1	50.0		5	3	60.0				
No	12	5	41.7		24	12	50.0				

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Table 2.3.4.2.10 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.06	(0.33,3.39)	1.03	(0.60,2.12) (0.59,1.81)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	0.73	(0.18,2.90)	0.87	(0.47,1.84) (0.49,1.56)	
Age					0.0574
>= 50 years	0.00	(0.00,1.35)	0.55	(0.23,1.27) (0.32,0.94)	
< 50 years	1.80	(0.45,7.45)	1.40	(0.65,5.18) (0.62,3.14)	
Race					0.3300
Asian	0.80	(0.17,3.74)	0.91	(0.46,1.99) (0.50,1.68)	
White	3.60	(0.35,98.27)	2.37	(0.56,64.70) (0.39,14.56)	
Region					0.3350
Europe + Africa + US	3.64	(0.36,98.33)	2.38	(0.61,65.60) (0.39,14.54)	
Asia(ex Japan) + Japan	0.83	(0.17,4.10)	0.93	(0.45,1.92) (0.50,1.73)	
BMI					0.1558
< 25 kg/m2	4.00	(0.65,25.80)	2.00	(0.83,8.73) (0.74,5.39)	
25 to < 30 kg/m2	0.33	(0.03,3.05)	0.60	(0.19,1.85) (0.23,1.55)	
>= 30 kg/m2	0.33	(0.01,6.19)	0.60	(0.17,4.27) (0.20,1.81)	
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.2.10 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	4	66.7	(30.0, 90.3)	8	5	62.5	(30.6, 86.3)	0.9864	-4.2	(-54.1,48.1)
No	11	4	36.4	(15.2, 64.6)	21	10	47.6	(28.3, 67.6)	0.7642	11.3	(-26.4,44.9)
Baseline GPPGA pustulation subscore											
<4	12	7	58.3	(32.0, 80.7)	22	13	59.1	(38.7, 76.7)	1.0000	0.8	(-33.2,35.9)
=4	6	2	33.3	(9.7, 70.0)	13	5	38.5	(17.7, 64.5)	0.9480	5.1	(-45.0,47.5)
Baseline GPPGA score											
=3	15	8	53.3	(30.1, 75.2)	28	16	57.1	(39.1, 73.5)	0.8503	3.8	(-27.0,35.0)
=4	3	1	33.3	(6.1, 79.2)	7	2	28.6	(8.2, 64.1)	1.0000	-4.8	(-70.8,53.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	9	60.0		29	16	55.2				
Background treatment prior to randomization											
Yes	8	2	25.0	(7.1, 59.1)	15	8	53.3	(30.1, 75.2)	0.3197	28.3	(-17.5,63.1)
No	10	7	70.0	(39.7, 89.2)	20	10	50.0	(29.9, 70.1)	0.3645	-20.0	(-52.8,20.2)
Pain VAS score at baseline											
<= 40	2	2	100.0		1	1	100.0				
> 40	16	7	43.8		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	9	50.0		32	16	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.10 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.5826
Yes	0.83	(0.07,8.69)	0.94	(0.35,2.79) (0.43,2.04)	
No	1.59	(0.34,7.82)	1.31	(0.55,7.53) (0.53,3.23)	
Baseline GPPGA pustulation subscore					0.8603
<4	1.03	(0.23,4.46)	1.01	(0.56,2.15) (0.56,1.83)	
=4	1.25	(0.15,12.77)	1.15	(0.32,7.12) (0.31,4.34)	
Baseline GPPGA score					0.8322
=3	1.17	(0.32,4.24)	1.07	(0.61,2.17) (0.60,1.90)	
=4	0.80	(0.04,34.87)	0.86	(0.10,23.16) (0.12,6.23)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.1315
Yes	3.43	(0.50,30.01)	2.13	(0.69,17.53) (0.59,7.75)	
No	0.43	(0.07,2.21)	0.71	(0.36,1.54) (0.39,1.30)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.10 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	7	43.8		26	13	50.0			
Mild	1	1	100.0		6	3	50.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.10 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.11 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	15	42.9	(28.0, 59.1)	0.0829	26.2	(-3.8,48.6)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	6	42.9	(21.4, 67.4)	0.2306	42.9	(-27.7,71.1)
Female	15	3	20.0	(7.0, 45.2)	21	9	42.9	(24.5, 63.5)	0.2009	22.9	(-11.5,51.0)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	3	27.3	(9.7, 56.6)	1.0000	2.3	(-55.5,46.5)
< 50 years	14	2	14.3	(4.0, 39.9)	24	12	50.0	(31.4, 68.6)	0.0344	35.7	(2.1,60.6)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	7	43.8	(23.1, 66.8)	0.3320	20.7	(-16.9,54.2)
White	5	0	0.0	(0.0, 43.4)	19	8	42.1	(23.1, 63.7)	0.1895	42.1	(-11.5,66.6)
Region											
Europe + Africa + US	5	0	0.0		21	9	42.9				
Asia(ex Japan) + Japan	13	3	23.1		14	6	42.9				
BMI											
< 25 kg/m2	9	1	11.1		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	2	16.7		24	9	37.5				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.11 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.75	(0.94,18.36)	2.57	(0.91,17.09) (0.85,7.74)	
Sex					NC
Male	inf	(0.50, inf)	inf	(0.55, inf)	
Female	3.00	(0.64,16.25)	2.14	(0.74,10.50) (0.69,6.61)	
Age					0.3351
>= 50 years	1.13	(0.08,39.00)	1.09	(0.16,28.32) (0.15,7.69)	
< 50 years	6.00	(1.13,44.82)	3.50	(1.02,31.61) (0.91,13.42)	
Race					NC
Asian	2.59	(0.49,15.21)	1.90	(0.60,11.78) (0.61,5.91)	
White	inf	(0.98, inf)	inf	(0.77, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.11 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	2	18.2	(5.1, 47.7)	21	8	38.1	(20.8, 59.1)	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	11	50.0	(30.7, 69.3)	0.0245	41.7	(6.6,65.7)
=4	6	2	33.3	(9.7, 70.0)	13	4	30.8	(12.7, 57.6)	1.0000	-2.6	(-51.7,40.0)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	14	50.0	(32.6, 67.4)	0.0874	30.0	(-2.1,55.3)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	3	20.0		29	13	44.8				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	5	33.3	(15.2, 58.3)	0.3866	20.8	(-24.2,52.9)
No	10	2	20.0	(5.7, 51.0)	20	10	50.0	(29.9, 70.1)	0.1361	30.0	(-12.0,59.7)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	14	41.2				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	14	43.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.11 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.6221
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					0.1224
<4	11.00	(1.40,258.77)	6.00	(1.10,167.09) (0.88,41.03)	
=4	0.89	(0.11,9.49)	0.92	(0.23,6.67) (0.23,3.72)	
Baseline GPPGA score					NC
=3	4.00	(0.93,20.42)	2.50	(0.94,17.77) (0.85,7.35)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9574
Yes	3.50	(0.36,94.38)	2.67	(0.49,69.03) (0.37,19.09)	
No	4.00	(0.68,32.08)	2.50	(0.79,27.08) (0.67,9.31)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.11 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	12	46.2			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.11 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.12 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	18	51.4	(35.6, 67.0)	0.0067	40.3	(9.6,60.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	10	47.6	(28.3, 67.6)	0.0417	34.3	(2.6,60.4)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	7	36.8	(19.1, 59.0)	0.1896	36.8	(-17.8,61.9)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	8	38.1	(20.8, 59.1)	0.1849	38.1	(-15.1,62.8)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	11	45.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.12 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.47	(1.80,59.33)	4.63	(1.21,52.13) (1.21,17.78)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	5.91	(1.09,44.76)	3.57	(1.06,38.68) (0.91,14.00)	
Age					0.2902
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(0.79, inf)	inf	(0.64, inf)	
Region					NC
Europe + Africa + US	inf	(0.85, inf)	inf	(0.69, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.2.12 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	1	16.7	(3.0, 56.4)	13	4	30.8	(12.7, 57.6)	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	15	53.6	(35.8, 70.5)	0.0168	40.2	(7.0,63.4)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	2	13.3		29	15	51.7				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	2	20.0	(5.7, 51.0)	20	11	55.0	(34.2, 74.2)	0.1143	35.0	(-5.4,65.2)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	16	50.0				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.12 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.8675
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.3092
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					NC
=3	7.50	(1.48,54.43)	4.02	(1.08,41.33) (1.06,15.28)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	4.89	(0.82,38.96)	2.75	(0.86,27.08) (0.75,10.11)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.2.12 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.12 Proportion of patients with DLQI personal relationship score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.13 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	7	20.0	(10.0, 35.9)	0.3093	14.4	(-9.3,32.9)
Sex											
Male	3	0	0.0		14	4	28.6				
Female	15	1	6.7		21	3	14.3				
Age											
>= 50 years	4	0	0.0		11	4	36.4				
< 50 years	14	1	7.1		24	3	12.5				
Race											
Asian	13	1	7.7		16	2	12.5				
White	5	0	0.0		19	5	26.3				
Region											
Europe + Africa + US	5	0	0.0		21	5	23.8				
Asia(ex Japan) + Japan	13	1	7.7		14	2	14.3				
BMI											
< 25 kg/m2	9	0	0.0		15	4	26.7				
25 to < 30 kg/m2	6	1	16.7		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	1	10.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	1	20.0				
No	12	1	8.3		24	4	16.7				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.13 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.25	(0.57,101.80)	3.60	(0.61,92.80) (0.48,27.05)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.13 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	0	0.0		8	2	25.0			
No	11	1	9.1		21	3	14.3			
Baseline GPPGA pustulation subscore										
<4	12	0	0.0		22	6	27.3			
=4	6	1	16.7		13	1	7.7			
Baseline GPPGA score										
=3	15	1	6.7		28	6	21.4			
=4	3	0	0.0		7	1	14.3			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	1	6.7		29	6	20.7			
Background treatment prior to randomization										
Yes	8	0	0.0		15	2	13.3			
No	10	1	10.0		20	5	25.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	0	0.0			
> 40	16	1	6.3		34	7	20.6			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	1	5.6		32	6	18.8			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.13 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			
Pain VAS score at baseline			
<= 40			
> 40			
Hepatic impairment at baseline			
Yes			
No			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.13 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	5	19.2			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.13 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.14 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	12	34.3	(20.8, 50.8)	0.0264	28.7	(2.2,47.9)
Sex											
Male	3	0	0.0		14	5	35.7				
Female	15	1	6.7		21	7	33.3				
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	3	27.3	(9.7, 56.6)	0.3537	27.3	(-33.5,61.0)
< 50 years	14	1	7.1	(1.3, 31.5)	24	9	37.5	(21.2, 57.3)	0.0631	30.4	(-1.3,53.9)
Race											
Asian	13	1	7.7		16	4	25.0				
White	5	0	0.0		19	8	42.1				
Region											
Europe + Africa + US	5	0	0.0		21	8	38.1				
Asia(ex Japan) + Japan	13	1	7.7		14	4	28.6				
BMI											
< 25 kg/m2	9	0	0.0		15	6	40.0				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	3	30.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	6	25.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.14 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.87	(1.29,201.76)	6.17	(1.02,168.54) (0.87,43.78)	
Sex					
Male					
Female					
Age					NC
>= 50 years	inf	(0.32, inf)	inf	(0.31, inf)	
< 50 years	7.80	(1.02,184.62)	5.25	(0.98,140.82) (0.74,37.20)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.14 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0		8	3	37.5				
No	11	1	9.1		21	6	28.6				
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	10	45.5	(26.9, 65.3)	0.0065	45.5	(13.3,67.8)
=4	6	1	16.7	(3.0, 56.4)	13	2	15.4	(4.3, 42.2)	1.0000	-1.3	(-47.5,34.4)
Baseline GPPGA score											
=3	15	1	6.7	(1.2, 29.8)	28	12	42.9	(26.5, 60.9)	0.0169	36.2	(5.0,57.8)
=4	3	0	0.0		7	0	0.0				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	1	16.7				
No	15	1	6.7		29	11	37.9				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	3	20.0	(7.0, 45.2)	0.3175	20.0	(-17.6,48.1)
No	10	1	10.0	(1.8, 40.4)	20	9	45.0	(25.8, 65.8)	0.0791	35.0	(-5.0,61.9)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	1	6.3		34	11	32.4				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	1	5.6		32	11	34.4				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.14 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(3.11, inf)	inf	(1.27, inf)	
=4	0.91	(0.06,31.93)	0.92	(0.09,24.95) (0.10,8.31)	
Baseline GPPGA score					NC
=3	10.50	(1.45,241.40)	6.43	(1.08,178.00) (0.92,44.79)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(0.48, inf)	inf	(0.42, inf)	
No	7.36	(0.89,179.46)	4.50	(0.86,122.26) (0.66,30.74)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.14 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	8	30.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.14 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.15 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	12	34.3	(20.8, 50.8)	0.0845	23.2	(-3.8,43.8)
Sex											
Male	3	0	0.0		14	5	35.7				
Female	15	2	13.3		21	7	33.3				
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	3	27.3	(9.7, 56.6)	1.0000	2.3	(-55.5,46.5)
< 50 years	14	1	7.1	(1.3, 31.5)	24	9	37.5	(21.2, 57.3)	0.0631	30.4	(-1.3,53.9)
Race											
Asian	13	2	15.4		16	6	37.5				
White	5	0	0.0		19	6	31.6				
Region											
Europe + Africa + US	5	0	0.0		21	7	33.3				
Asia(ex Japan) + Japan	13	2	15.4		14	5	35.7				
BMI											
< 25 kg/m2	9	0	0.0		15	6	40.0				
25 to < 30 kg/m2	6	2	33.3		10	2	20.0				
>= 30 kg/m2	3	0	0.0		10	4	40.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	1	8.3		24	8	33.3				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.15 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	4.17	(0.87,30.05)	3.09	(0.87,27.91) (0.77,12.32)	
Sex					
Male					
Female					
Age					0.2654
>= 50 years	1.13	(0.08,39.00)	1.09	(0.16,28.32) (0.15,7.69)	
< 50 years	7.80	(1.02,184.62)	5.25	(0.98,140.82) (0.74,37.20)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.15 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	1	16.7		8	4	50.0			
No	11	1	9.1		21	7	33.3			
Baseline GPPGA pustulation subscore										
<4	12	1	8.3	(1.5, 35.4)	22	11	50.0	(30.7, 69.3)	0.0245	41.7 (6.6,65.7)
=4	6	1	16.7	(3.0, 56.4)	13	1	7.7	(1.4, 33.3)	0.8189	-9.0 (-54.7,25.5)
Baseline GPPGA score										
=3	15	2	13.3	(3.7, 37.9)	28	12	42.9	(26.5, 60.9)	0.0874	29.5 (-2.0,53.0)
=4	3	0	0.0		7	0	0.0			
Baseline plaque psoriasis										
Yes	3	0	0.0		6	1	16.7			
No	15	2	13.3		29	11	37.9			
Background treatment prior to randomization										
Yes	8	0	0.0		15	5	33.3			
No	10	2	20.0		20	7	35.0			
Pain VAS score at baseline										
<= 40	2	0	0.0		1	1	100.0			
> 40	16	2	12.5		34	11	32.4			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	2	11.1		32	12	37.5			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.15 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.1198
<4	11.00	(1.40,258.77)	6.00	(1.10,167.09) (0.88,41.03)	
=4	0.42	(0.01,19.39)	0.46	(0.01,15.12) (0.03,6.20)	
Baseline GPPGA score					NC
=3	4.88	(0.96,35.90)	3.21	(0.94,29.05) (0.83,12.51)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.15 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	9	34.6			
Mild	1	0	0.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.15 Proportion of patients with DLQI symptoms and feelings score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.16 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	6	33.3	(16.3, 56.3)	35	19	54.3	(38.2, 69.5)	0.1770	21.0	(-8.8,46.5)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	9	64.3	(38.8, 83.7)	0.1526	64.3	(-10.0,90.5)
Female	15	6	40.0	(19.8, 64.3)	21	10	47.6	(28.3, 67.6)	0.7226	7.6	(-27.6,39.5)
Age											
>= 50 years	4	2	50.0	(15.0, 85.0)	11	6	54.5	(28.0, 78.7)	0.9635	4.5	(-50.5,58.5)
< 50 years	14	4	28.6	(11.7, 54.6)	24	13	54.2	(35.1, 72.1)	0.1663	25.6	(-8.3,54.4)
Race											
Asian	13	6	46.2	(23.2, 70.9)	16	8	50.0	(28.0, 72.0)	0.9234	3.8	(-33.1,39.8)
White	5	0	0.0	(0.0, 43.4)	19	11	57.9	(36.3, 76.9)	0.0394	57.9	(1.8,79.8)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	12	57.1	(36.5, 75.5)	0.0329	57.1	(3.1,79.0)
Asia(ex Japan) + Japan	13	6	46.2	(23.2, 70.9)	14	7	50.0	(26.8, 73.2)	0.9423	3.8	(-34.6,41.8)
BMI											
< 25 kg/m2	9	3	33.3	(12.1, 64.6)	15	10	66.7	(41.7, 84.8)	0.1604	33.3	(-9.8,67.8)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	4	40.0	(16.8, 68.7)	0.8833	6.7	(-45.6,52.2)
>= 30 kg/m2	3	1	33.3	(6.1, 79.2)	10	5	50.0	(23.7, 76.3)	0.9951	16.7	(-47.7,67.4)
Mutation status IL36RN											
Yes	2	0	0.0		5	3	60.0				
No	12	6	50.0		24	13	54.2				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.16 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.38	(0.72,8.17)	1.63	(0.83,6.48) (0.79,3.35)	
Sex					NC
Male	inf	(1.13, inf)	inf	(0.88, inf)	
Female	1.36	(0.34,5.49)	1.19	(0.55,2.94) (0.55,2.56)	
Age					0.4518
>= 50 years	1.20	(0.09,15.09)	1.09	(0.36,11.87) (0.36,3.34)	
< 50 years	2.95	(0.71,13.27)	1.90	(0.83,8.55) (0.77,4.69)	
Race					NC
Asian	1.17	(0.26,5.33)	1.08	(0.46,2.61) (0.50,2.33)	
White	inf	(1.82, inf)	inf	(1.02, inf)	
Region					NC
Europe + Africa + US	inf	(1.81, inf)	inf	(0.98, inf)	
Asia(ex Japan) + Japan	1.17	(0.24,5.59)	1.08	(0.46,2.76) (0.49,2.38)	
BMI					0.8326
< 25 kg/m2	4.00	(0.65,25.80)	2.00	(0.83,8.73) (0.74,5.39)	
25 to < 30 kg/m2	1.33	(0.15,14.54)	1.20	(0.30,8.57) (0.31,4.69)	
>= 30 kg/m2	2.00	(0.11,70.07)	1.50	(0.37,39.93) (0.27,8.34)	
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.2.16 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	5	62.5	(30.6, 86.3)	0.1299	45.8	(-10.0,83.0)
No	11	5	45.5	(21.3, 72.0)	21	11	52.4	(32.4, 71.7)	0.8409	6.9	(-29.8,41.9)
Baseline GPPGA pustulation subscore											
<4	12	5	41.7	(19.3, 68.0)	22	10	45.5	(26.9, 65.3)	0.8853	3.8	(-31.9,37.6)
=4	6	1	16.7	(3.0, 56.4)	13	9	69.2	(42.4, 87.3)	0.0624	52.6	(-4.3,82.8)
Baseline GPPGA score											
=3	15	6	40.0	(19.8, 64.3)	28	15	53.6	(35.8, 70.5)	0.4359	13.6	(-19.2,42.9)
=4	3	0	0.0	(0.0, 56.1)	7	4	57.1	(25.0, 84.2)	0.1336	57.1	(-22.9,90.5)
Baseline plaque psoriasis											
Yes	3	1	33.3		6	3	50.0				
No	15	5	33.3		29	16	55.2				
Background treatment prior to randomization											
Yes	8	2	25.0	(7.1, 59.1)	15	9	60.0	(35.7, 80.2)	0.1469	35.0	(-11.1,68.7)
No	10	4	40.0	(16.8, 68.7)	20	10	50.0	(29.9, 70.1)	0.7850	10.0	(-28.9,45.1)
Pain VAS score at baseline											
<= 40	2	1	50.0		1	1	100.0				
> 40	16	5	31.3		34	18	52.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	6	33.3		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.2.16 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.2519
Yes	8.33	(0.61,234.27)	3.75	(0.78,102.33) (0.58,24.28)	
No	1.32	(0.29,6.08)	1.15	(0.53,3.64) (0.54,2.48)	
Baseline GPPGA pustulation subscore					0.1896
<4	1.17	(0.27,5.18)	1.09	(0.48,3.28) (0.48,2.45)	
=4	11.25	(0.98,294.01)	4.15	(0.95,119.28) (0.67,25.78)	
Baseline GPPGA score					NC
=3	1.73	(0.47,6.49)	1.34	(0.69,3.92) (0.66,2.72)	
=4	inf	(0.68, inf)	inf	(0.67, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.4072
Yes	4.50	(0.64,39.15)	2.40	(0.81,17.53) (0.67,8.54)	
No	1.50	(0.31,7.67)	1.25	(0.54,7.18) (0.52,3.00)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.4.2.16 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	4	25.0		26	14	53.8			
Mild	1	1	100.0		6	3	50.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.16 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.17 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	20	57.1	(40.9, 72.0)	0.0067	40.5	(9.5,61.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	13	61.9	(40.9, 79.2)	0.0200	41.9	(8.1,67.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	2	14.3	(4.0, 39.9)	24	14	58.3	(38.8, 75.5)	0.0098	44.0	(7.1,67.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	10	62.5	(38.6, 81.5)	0.0410	39.4	(1.5,69.1)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	9	64.3	(38.8, 83.7)	0.0378	41.2	(2.0,72.6)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	10	66.7	(41.7, 84.8)	0.0151	55.6	(11.8,81.5)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	4	40.0	(16.8, 68.7)	0.8833	6.7	(-45.6,52.2)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	11	45.8				

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Table 2.3.4.2.17 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.67	(1.66,32.22)	3.43	(1.11,22.47) (1.17,10.02)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	6.50	(1.37,34.65)	3.10	(1.12,22.60) (1.07,8.99)	
Age					0.5802
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	8.40	(1.57,62.24)	4.08	(1.14,45.03) (1.08,15.39)	
Race					NC
Asian	5.56	(1.04,32.17)	2.71	(1.04,11.86) (0.94,7.84)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	6.00	(1.06,36.18)	2.79	(1.04,13.48) (0.96,8.09)	
BMI					NC
< 25 kg/m2	16.00	(1.65,389.52)	6.00	(1.15,172.26) (0.91,39.41)	
25 to < 30 kg/m2	1.33	(0.15,14.54)	1.20	(0.30,8.57) (0.31,4.69)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.3.4.2.17 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	9	42.9	(24.5, 63.5)	0.3134	24.7	(-12.2,53.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	14	63.6	(43.0, 80.3)	0.0040	55.3	(14.9,77.7)
=4	6	2	33.3	(9.7, 70.0)	13	6	46.2	(23.2, 70.9)	0.8190	12.8	(-38.0,54.7)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	18	64.3	(45.8, 79.3)	0.0071	44.3	(7.0,68.0)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	3	20.0		29	17	58.6				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	7	46.7	(24.8, 69.9)	0.1244	34.2	(-8.6,65.1)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	3	18.8		34	19	55.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	18	56.3				

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Table 2.3.4.2.17 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4864
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	3.38	(0.59,26.83)	2.36	(0.71,19.32) (0.61,9.07)	
Baseline GPPGA pustulation subscore					0.1440
<4	19.25	(2.38,444.55)	7.64	(1.38,223.47) (1.14,51.21)	
=4	1.71	(0.21,17.04)	1.38	(0.40,15.12) (0.39,4.95)	
Baseline GPPGA score					NC
=3	7.20	(1.63,36.65)	3.21	(1.13,17.77) (1.13,9.18)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9060
Yes	6.13	(0.65,157.44)	3.73	(0.76,100.06) (0.55,25.25)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.4.2.17 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	16	61.5			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.17 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.18 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	19	54.3	(38.2, 69.5)	0.0052	43.2	(9.6,63.6)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	8	57.1	(32.6, 78.6)	0.1596	57.1	(-19.1,82.3)
Female	15	2	13.3	(3.7, 37.9)	21	11	52.4	(32.4, 71.7)	0.0200	39.0	(5.0,64.6)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	6	54.5	(28.0, 78.7)	0.4029	29.5	(-33.3,71.2)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	11	68.8	(44.4, 85.8)	0.0043	53.4	(17.1,79.2)
White	5	0	0.0	(0.0, 43.4)	19	8	42.1	(23.1, 63.7)	0.1895	42.1	(-11.5,66.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	9	42.9	(24.5, 63.5)	0.1718	42.9	(-9.2,67.1)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	10	71.4	(45.4, 88.3)	0.0039	56.0	(15.9,82.9)
BMI											
< 25 kg/m2	9	0	0.0		15	9	60.0				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	11	45.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.18 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	9.50	(2.01,66.39)	4.89	(1.35,52.13) (1.28,18.69)	
Sex					NC
Male	inf	(0.87, inf)	inf	(0.77, inf)	
Female	7.15	(1.31,53.78)	3.93	(1.12,38.68) (1.02,15.20)	
Age					0.3517
>= 50 years	3.60	(0.26,109.41)	2.18	(0.53,58.97) (0.37,12.95)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	12.10	(1.88,96.05)	4.47	(1.34,43.94) (1.20,16.68)	
White	inf	(0.98, inf)	inf	(0.77, inf)	
Region					NC
Europe + Africa + US	inf	(1.04, inf)	inf	(0.76, inf)	
Asia(ex Japan) + Japan	13.75	(1.99,112.67)	4.64	(1.33,50.18) (1.24,17.33)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.2.18 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	6	75.0	(40.9, 92.9)	0.0430	58.3	(1.8,90.2)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	1	16.7	(3.0, 56.4)	13	6	46.2	(23.2, 70.9)	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	16	57.1	(39.1, 73.5)	0.0070	43.8	(7.0,66.5)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	15	51.7				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	6	40.0	(19.8, 64.3)	0.0412	40.0	(1.8,67.7)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	18	52.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	17	53.1				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.18 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9727
Yes	15.00	(0.97,409.05)	4.50	(1.03,128.53) (0.72,28.15)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59) (0.68,32.57)	
Baseline GPPGA pustulation subscore					0.4919
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					NC
=3	8.67	(1.70,62.73)	4.29	(1.13,41.33) (1.13,16.20)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.45, inf)	inf	(0.92, inf)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.4.2.18 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	15	57.7			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.18 Proportion of patients with DLQI treatment score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	10	55.6	(33.7, 75.4)	35	10	28.6	(16.3, 45.1)	0.0829	-27.0 (-53.5,1.5)
Sex										
Male	3	1	33.3	(6.1, 79.2)	14	4	28.6	(11.7, 54.6)	1.0000	-4.8 (-64.8,42.6)
Female	15	9	60.0	(35.7, 80.2)	21	6	28.6	(13.8, 50.0)	0.0727	-31.4 (-61.1,2.6)
Age										
>= 50 years	4	3	75.0	(30.1, 95.4)	11	4	36.4	(15.2, 64.6)	0.2582	-38.6 (-80.6,24.0)
< 50 years	14	7	50.0	(26.8, 73.2)	24	6	25.0	(12.0, 44.9)	0.1663	-25.0 (-55.3,7.3)
Race										
Asian	13	7	53.8	(29.1, 76.8)	16	4	25.0	(10.2, 49.5)	0.1666	-28.8 (-61.4,10.1)
White	5	3	60.0	(23.1, 88.2)	19	6	31.6	(15.4, 54.0)	0.3193	-28.4 (-68.4,20.3)
Region										
Europe + Africa + US	5	3	60.0	(23.1, 88.2)	21	6	28.6	(13.8, 50.0)	0.2273	-31.4 (-71.6,17.1)
Asia(ex Japan) + Japan	13	7	53.8	(29.1, 76.8)	14	4	28.6	(11.7, 54.6)	0.2543	-25.3 (-59.1,14.2)
BMI										
< 25 kg/m2	9	6	66.7	(35.4, 87.9)	15	4	26.7	(10.9, 52.0)	0.0676	-40.0 (-73.4,2.7)
25 to < 30 kg/m2	6	3	50.0	(18.8, 81.2)	10	3	30.0	(10.8, 60.3)	0.7015	-20.0 (-65.4,31.0)
>= 30 kg/m2	3	1	33.3	(6.1, 79.2)	10	3	30.0	(10.8, 60.3)	1.0000	-3.3 (-64.8,50.3)
Mutation status IL36RN										
Yes	2	1	50.0		5	2	40.0			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.32	(0.10,1.08)	0.51	(0.25,1.05) (0.26,1.00)	
Sex					0.5584
Male	0.80	(0.05,29.23)	0.86	(0.16,22.08) (0.14,5.20)	
Female	0.27	(0.06,1.13)	0.48	(0.18,1.05) (0.22,1.05)	
Age					0.9630
>= 50 years	0.19	(0.01,2.70)	0.48	(0.14,1.84) (0.18,1.27)	
< 50 years	0.33	(0.08,1.42)	0.50	(0.19,1.30) (0.21,1.19)	
Race					0.8593
Asian	0.29	(0.06,1.45)	0.46	(0.13,1.24) (0.17,1.25)	
White	0.31	(0.03,2.72)	0.53	(0.19,3.83) (0.20,1.40)	
Region					0.8780
Europe + Africa + US	0.27	(0.03,2.34)	0.48	(0.17,3.47) (0.18,1.27)	
Asia(ex Japan) + Japan	0.34	(0.06,1.78)	0.53	(0.15,1.39) (0.20,1.40)	
BMI					0.7148
< 25 kg/m2	0.18	(0.03,1.18)	0.40	(0.11,1.07) (0.15,1.04)	
25 to < 30 kg/m2	0.43	(0.05,4.08)	0.60	(0.14,2.61) (0.17,2.07)	
>= 30 kg/m2	0.86	(0.05,33.33)	0.90	(0.15,23.43) (0.14,5.78)	
Mutation status IL36RN Yes					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
No	12	8	66.7		24	8	33.3			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Mutation status IL36RN after DNA resequencing										
Yes	6	4	66.7	(30.0, 90.3)	8	3	37.5	(13.7, 69.4)	0.4163	-29.2 (-73.1,27.0)
No	11	6	54.5	(28.0, 78.7)	21	7	33.3	(17.2, 54.6)	0.3829	-21.2 (-54.7,15.9)
Baseline GPPGA pustulation subscore										
<4	12	7	58.3	(32.0, 80.7)	22	8	36.4	(19.7, 57.0)	0.3271	-22.0 (-54.0,14.5)
=4	6	3	50.0	(18.8, 81.2)	13	2	15.4	(4.3, 42.2)	0.1509	-34.6 (-75.4,11.2)
Baseline GPPGA score										
=3	15	8	53.3	(30.1, 75.2)	28	9	32.1	(17.9, 50.7)	0.3198	-21.2 (-50.5,10.7)
=4	3	2	66.7	(20.8, 93.9)	7	1	14.3	(2.6, 51.3)	0.1823	-52.4 (-93.2,16.9)
Baseline plaque psoriasis										
Yes	3	1	33.3		6	1	16.7			
No	15	9	60.0		29	9	31.0			
Background treatment prior to randomization										
Yes	8	4	50.0	(21.5, 78.5)	15	5	33.3	(15.2, 58.3)	0.5266	-16.7 (-56.5,26.0)
No	10	6	60.0	(31.3, 83.2)	20	5	25.0	(11.2, 46.9)	0.1143	-35.0 (-67.1,5.0)
Pain VAS score at baseline										
<= 40	2	2	100.0		1	1	100.0			
> 40	16	8	50.0		34	9	26.5			
Hepatic impairment at baseline										
Yes	0	0	na		0	0	na			
No	18	10	55.6		32	10	31.3			

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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.9030
Yes	0.30	(0.03,3.10)	0.56	(0.14,2.04) (0.20,1.62)	
No	0.42	(0.09,1.97)	0.61	(0.26,1.60) (0.27,1.37)	
Baseline GPPGA pustulation subscore					0.4082
<4	0.41	(0.09,1.81)	0.62	(0.28,1.64) (0.30,1.29)	
=4	0.18	(0.02,1.93)	0.31	(0.03,1.62) (0.07,1.39)	
Baseline GPPGA score					0.3365
=3	0.41	(0.11,1.57)	0.60	(0.28,1.42) (0.29,1.23)	
=4	0.08	(0.00,2.65)	0.21	(0.01,1.88) (0.03,1.56)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.4953
Yes	0.50	(0.08,3.21)	0.67	(0.21,2.14) (0.25,1.81)	
No	0.22	(0.04,1.20)	0.42	(0.15,1.20) (0.17,1.04)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	8	50.0		26	7	26.9			
Mild	1	1	100.0		6	1	16.7			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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inf = infinity. NC = not calculable

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Table 2.3.4.2.19 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 1 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.20 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	16	45.7	(30.5, 61.8)	0.0163	34.6	(5.8,55.4)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	5	35.7	(16.3, 61.2)	0.3501	35.7	(-35.2,66.5)
Female	15	2	13.3	(3.7, 37.9)	21	11	52.4	(32.4, 71.7)	0.0200	39.0	(5.0,64.6)
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	5	45.5	(21.3, 72.0)	0.2581	45.5	(-15.3,76.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	11	45.8	(27.9, 64.9)	0.0633	31.5	(-1.3,56.7)
Race											
Asian	13	2	15.4		16	7	43.8				
White	5	0	0.0		19	9	47.4				
Region											
Europe + Africa + US	5	0	0.0		21	9	42.9				
Asia(ex Japan) + Japan	13	2	15.4		14	7	50.0				
BMI											
< 25 kg/m2	9	1	11.1		15	7	46.7				
25 to < 30 kg/m2	6	1	16.7		10	3	30.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	8	33.3				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.2.20 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.74	(1.43,47.48)	4.11	(1.06,39.66) (1.06,15.96)	
Sex					NC
Male	inf	(0.37, inf)	inf	(0.40, inf)	
Female	7.15	(1.31,53.78)	3.93	(1.12,38.68) (1.02,15.20)	
Age					NC
>= 50 years	inf	(0.74, inf)	inf	(0.64, inf)	
< 50 years	5.08	(0.96,38.17)	3.21	(0.92,31.61) (0.83,12.44)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.20 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	n	%	(95% CI)	Speso 900 mg IV SD N	n	%	(95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0		8	6	75.0				
No	11	2	18.2		21	7	33.3				
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	12	54.5	(34.7, 73.1)	0.0016	54.5	(21.1,75.6)
=4	6	2	33.3	(9.7, 70.0)	13	4	30.8	(12.7, 57.6)	1.0000	-2.6	(-51.7,40.0)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	15	53.6	(35.8, 70.5)	0.0168	40.2	(7.0,63.4)
=4	3	0	0.0	(0.0, 56.1)	7	1	14.3	(2.6, 51.3)	0.8467	14.3	(-54.0,58.9)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	2	13.3		29	13	44.8				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	6	40.0	(19.8, 64.3)	0.3175	27.5	(-15.9,59.1)
No	10	1	10.0	(1.8, 40.4)	20	10	50.0	(29.9, 70.1)	0.0383	40.0	(2.0,66.3)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	2	12.5		34	15	44.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	14	43.8				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.4.2.20 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					NC
<4	inf	(4.44, inf)	inf	(1.75, inf)	
=4	0.89	(0.11,9.49)	0.92	(0.23,6.67) (0.23,3.72)	
Baseline GPPGA score					NC
=3	7.50	(1.48,54.43)	4.02	(1.08,41.33) (1.06,15.28)	
=4	inf	(0.05, inf)	inf	(0.03, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7477
Yes	4.67	(0.49,122.42)	3.20	(0.62,84.14) (0.46,22.16)	
No	9.00	(1.08,217.16)	5.00	(1.03,138.20) (0.74,33.78)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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Table 2.3.4.2.20 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	12	46.2			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.4.2.20 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 4 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.4.2.21 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	(1.0, 25.8)	35	18	51.4	(35.6, 67.0)	0.0015	45.9	(17.1,64.6)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	1	6.7	(1.2, 29.8)	21	11	52.4	(32.4, 71.7)	0.0068	45.7	(15.1,69.3)
Age											
>= 50 years	4	0	0.0	(0.0, 49.0)	11	5	45.5	(21.3, 72.0)	0.2581	45.5	(-15.3,76.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	13	1	7.7	(1.4, 33.3)	16	9	56.3	(33.2, 76.9)	0.0097	48.6	(11.0,75.1)
White	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	10	47.6	(28.3, 67.6)	0.1717	47.6	(-9.2,71.6)
Asia(ex Japan) + Japan	13	1	7.7	(1.4, 33.3)	14	8	57.1	(32.6, 78.6)	0.0069	49.5	(12.3,77.1)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	1	16.7		10	4	40.0				
>= 30 kg/m2	3	0	0.0		10	6	60.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	1	8.3		24	10	41.7				

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Table 2.3.4.2.21 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	18.00	(2.65,399.14)	9.26	(1.69,269.81) (1.34,63.89)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	15.40	(1.98,355.95)	7.86	(1.27,219.78) (1.13,54.51)	
Age					NC
>= 50 years	inf	(0.74, inf)	inf	(0.64, inf)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	15.43	(1.78,366.32)	7.31	(1.23,203.01) (1.06,50.48)	
White	inf	(1.22, inf)	inf	(0.84, inf)	
Region					NC
Europe + Africa + US	inf	(1.25, inf)	inf	(0.82, inf)	
Asia(ex Japan) + Japan	16.00	(1.75,384.19)	7.43	(1.33,204.92) (1.07,51.54)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.21 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	0	0.0	(0.0, 39.0)	8	6	75.0	(40.9, 92.9)	0.0054	75.0	(23.4,96.8)
No	11	1	9.1	(1.6, 37.7)	21	9	42.9	(24.5, 63.5)	0.0818	33.8	(-2.3,60.2)
Baseline GPPGA pustulation subscore											
<4	12	0	0.0	(0.0, 24.2)	22	13	59.1	(38.7, 76.7)	0.0010	59.1	(21.1,79.3)
=4	6	1	16.7	(3.0, 56.4)	13	5	38.5	(17.7, 64.5)	0.4859	21.8	(-28.2,58.2)
Baseline GPPGA score											
=3	15	1	6.7	(1.2, 29.8)	28	16	57.1	(39.1, 73.5)	0.0019	50.5	(16.3,70.6)
=4	3	0	0.0	(0.0, 56.1)	7	2	28.6	(8.2, 64.1)	0.4865	28.6	(-41.8,71.0)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	1	6.7		29	14	48.3				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	7	46.7	(24.8, 69.9)	0.0350	46.7	(2.6,73.4)
No	10	1	10.0	(1.8, 40.4)	20	11	55.0	(34.2, 74.2)	0.0340	45.0	(2.3,70.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	1	100.0				
> 40	16	1	6.3		34	17	50.0				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	1	5.6		32	16	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.21 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					NC
Yes	inf	(3.16, inf)	inf	(1.55, inf)	
No	7.50	(0.93,181.07)	4.71	(0.93,127.59)	
				(0.68,32.57)	
Baseline GPPGA pustulation subscore					NC
<4	inf	(5.29, inf)	inf	(2.07, inf)	
=4	3.13	(0.29,88.28)	2.31	(0.45,60.18)	
				(0.34,15.69)	
Baseline GPPGA score					NC
=3	18.67	(2.56,420.90)	8.57	(1.62,250.03)	
				(1.26,58.49)	
=4	inf	(0.19, inf)	inf	(0.18, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.90, inf)	inf	(1.07, inf)	
No	11.00	(1.32,263.20)	5.50	(1.05,154.74)	
				(0.82,36.82)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.21 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	1	6.3		26	14	53.8			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.4.2.21 Proportion of patients with DLQI work and school score of 0 or 1 overall and by subgroup at week 12 - RS (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline					
Normal					
Mild					
Moderate					
Severe					
ESRD					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.3.5 EQ-5D(-5L) score

Table 2.3.5.1 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	9	50.0	(29.0, 71.0)	33	23	69.7	(52.7, 82.6)	0.1857	19.7	(-9.0,47.6)
Sex											
Male	3	2	66.7	(20.8, 93.9)	13	8	61.5	(35.5, 82.3)	1.0000	-5.1	(-53.3,56.5)
Female	15	7	46.7	(24.8, 69.9)	20	15	75.0	(53.1, 88.8)	0.1009	28.3	(-5.6,58.2)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	5	55.6	(26.7, 81.1)	0.4858	30.6	(-33.9,74.1)
< 50 years	14	8	57.1	(32.6, 78.6)	24	18	75.0	(55.1, 88.0)	0.3466	17.9	(-13.4,49.0)
Race											
Asian	13	6	46.2	(23.2, 70.9)	16	9	56.3	(33.2, 76.9)	0.6372	10.1	(-27.1,45.6)
White	5	3	60.0	(23.1, 88.2)	17	14	82.4	(59.0, 93.8)	0.3581	22.4	(-20.6,68.2)
Region											
Europe + Africa + US	5	3	60.0	(23.1, 88.2)	19	15	78.9	(56.7, 91.5)	0.5229	18.9	(-23.9,65.3)
Asia(ex Japan) + Japan	13	6	46.2	(23.2, 70.9)	14	8	57.1	(32.6, 78.6)	0.6898	11.0	(-29.5,47.7)
BMI											
< 25 kg/m2	9	5	55.6	(26.7, 81.1)	14	9	64.3	(38.8, 83.7)	0.7402	8.7	(-32.2,49.5)
25 to < 30 kg/m2	6	4	66.7	(30.0, 90.3)	10	7	70.0	(39.7, 89.2)	1.0000	3.3	(-43.0,53.2)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	9	7	77.8	(45.3, 93.7)	0.0403	77.8	(2.6,97.2)
Mutation status IL36RN											
Yes	2	1	50.0		5	5	100.0				
No	12	6	50.0		22	14	63.6				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.1 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.30	(0.68,7.70)	1.39	(0.86,2.92) (0.83,2.33)	
Sex					0.3174
Male	0.80	(0.02,13.23)	0.92	(0.41,7.57) (0.37,2.29)	
Female	3.43	(0.78,15.13)	1.61	(0.89,3.68) (0.88,2.92)	
Age					0.5802
>= 50 years	3.75	(0.25,117.01)	2.22	(0.50,59.74) (0.37,13.38)	
< 50 years	2.25	(0.52,9.54)	1.31	(0.81,2.65) (0.79,2.18)	
Race					0.8236
Asian	1.50	(0.33,6.88)	1.22	(0.58,3.05) (0.59,2.53)	
White	3.11	(0.25,30.07)	1.37	(0.77,9.57) (0.65,2.90)	
Region					0.9101
Europe + Africa + US	2.50	(0.22,22.15)	1.32	(0.73,8.69) (0.62,2.79)	
Asia(ex Japan) + Japan	1.56	(0.32,7.52)	1.24	(0.53,2.94) (0.59,2.60)	
BMI					NC
< 25 kg/m2	1.44	(0.24,8.51)	1.16	(0.57,3.25) (0.57,2.34)	
25 to < 30 kg/m2	1.17	(0.10,11.39)	1.05	(0.49,3.04) (0.52,2.11)	
>= 30 kg/m2	inf	(1.64, inf)	inf	(1.04, inf)	
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.1 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	3	50.0	(18.8, 81.2)	8	7	87.5	(52.9, 97.8)	0.2159	37.5	(-17.9,79.2)
No	11	6	54.5	(28.0, 78.7)	19	12	63.2	(41.0, 80.9)	0.7863	8.6	(-28.0,44.6)
Baseline GPPGA pustulation subscore											
<4	12	4	33.3	(13.8, 60.9)	21	14	66.7	(45.4, 82.8)	0.0950	33.3	(-3.8,63.5)
=4	6	5	83.3	(43.6, 97.0)	12	9	75.0	(46.8, 91.1)	0.8599	-8.3	(-46.1,39.8)
Baseline GPPGA score											
=3	15	7	46.7		27	20	74.1				
=4	3	2	66.7		6	3	50.0				
Baseline plaque psoriasis											
Yes	3	2	66.7		6	4	66.7				
No	15	7	46.7		27	19	70.4				
Background treatment prior to randomization											
Yes	8	3	37.5	(13.7, 69.4)	13	8	61.5	(35.5, 82.3)	0.4472	24.0	(-21.7,62.8)
No	10	6	60.0	(31.3, 83.2)	20	15	75.0	(53.1, 88.8)	0.4622	15.0	(-20.5,52.0)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	9	56.3		32	23	71.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	9	50.0		30	20	66.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
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Table 2.3.5.1 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4439
Yes	7.00	(0.45,207.94)	1.75	(0.80,10.53) (0.75,4.06)	
No	1.43	(0.29,6.77)	1.16	(0.61,2.92) (0.61,2.19)	
Baseline GPPGA pustulation subscore					0.1114
<4	4.00	(0.85,19.39)	2.00	(0.92,8.40) (0.85,4.70)	
=4	0.60	(0.02,7.55)	0.90	(0.51,2.00) (0.55,1.46)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6405
Yes	2.67	(0.40,18.43)	1.64	(0.62,8.89) (0.61,4.43)	
No	2.00	(0.35,10.63)	1.25	(0.74,3.12) (0.71,2.20)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.5.1 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	9	56.3		25	20	80.0			
Mild	1	0	0.0		5	2	40.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.1 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.2 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	33	18	54.5	(38.0, 70.2)	0.0101	37.9	(5.6,60.1)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	5	38.5	(17.7, 64.5)	0.2865	38.5	(-30.2,70.8)
Female	15	3	20.0	(7.0, 45.2)	20	13	65.0	(43.3, 81.9)	0.0092	45.0	(9.7,70.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	5	55.6	(26.7, 81.1)	0.4858	30.6	(-33.9,74.1)
< 50 years	14	2	14.3	(4.0, 39.9)	24	13	54.2	(35.1, 72.1)	0.0221	39.9	(4.4,64.9)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	8	50.0	(28.0, 72.0)	0.1669	26.9	(-10.2,58.9)
White	5	0	0.0	(0.0, 43.4)	17	10	58.8	(36.0, 78.4)	0.0341	58.8	(2.3,81.9)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	11	57.9	(36.3, 76.9)	0.0394	57.9	(1.8,79.8)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	7	50.0	(26.8, 73.2)	0.1993	26.9	(-11.0,60.2)
BMI											
< 25 kg/m2	9	1	11.1		14	8	57.1				
25 to < 30 kg/m2	6	2	33.3		10	4	40.0				
>= 30 kg/m2	3	0	0.0		9	6	66.7				
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		22	10	45.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.2 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.00	(1.48,29.23)	3.27	(1.11,18.12) (1.11,9.63)	
Sex					NC
Male	inf	(0.41, inf)	inf	(0.44, inf)	
Female	7.43	(1.52,40.11)	3.25	(1.19,23.31) (1.12,9.40)	
Age					0.6397
>= 50 years	3.75	(0.25,117.01)	2.22	(0.50,59.74) (0.37,13.38)	
< 50 years	7.09	(1.34,52.71)	3.79	(1.08,38.38) (1.00,14.41)	
Race					NC
Asian	3.33	(0.64,19.32)	2.17	(0.76,11.85) (0.72,6.55)	
White	inf	(1.84, inf)	inf	(1.03, inf)	
Region					NC
Europe + Africa + US	inf	(1.82, inf)	inf	(1.02, inf)	
Asia(ex Japan) + Japan	3.33	(0.61,20.00)	2.17	(0.70,13.40) (0.71,6.66)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.2 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	19	8	42.1	(23.1, 63.7)	0.2287	23.9	(-14.4,53.6)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	21	13	61.9	(40.9, 79.2)	0.0050	53.6	(14.7,76.3)
=4	6	2	33.3	(9.7, 70.0)	12	5	41.7	(19.3, 68.0)	0.8729	8.3	(-42.6,51.5)
Baseline GPPGA score											
=3	15	3	20.0		27	17	63.0				
=4	3	0	0.0		6	1	16.7				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	2	33.3				
No	15	3	20.0		27	16	59.3				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	13	6	46.2	(23.2, 70.9)	0.1631	33.7	(-11.7,66.6)
No	10	2	20.0	(5.7, 51.0)	20	12	60.0	(38.7, 78.1)	0.0751	40.0	(-1.9,68.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	3	18.8		32	18	56.3				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		30	16	53.3				

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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.2 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4783
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	3.27	(0.55,26.49)	2.32	(0.67,19.10) (0.59,9.02)	
Baseline GPPGA pustulation subscore					0.1315
<4	17.88	(2.19,414.84)	7.43	(1.38,215.14) (1.10,49.98)	
=4	1.43	(0.17,14.70)	1.25	(0.35,7.71) (0.34,4.65)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8606
Yes	6.00	(0.60,157.25)	3.69	(0.74,98.06) (0.54,25.31)	
No	6.00	(1.00,47.64)	3.00	(0.94,27.08) (0.83,10.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.2 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo	
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		25	15	60.0			
Mild	1	0	0.0		5	2	40.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.2 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.3 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	2	11.1	(3.1, 32.8)	33	17	51.5	(35.2, 67.5)	0.0069	40.4	(9.4,60.9)
Sex											
Male	3	0	0.0	(0.0, 56.1)	13	6	46.2	(23.2, 70.9)	0.1941	46.2	(-22.3,75.7)
Female	15	2	13.3	(3.7, 37.9)	20	11	55.0	(34.2, 74.2)	0.0136	41.7	(8.8,67.7)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	9	5	55.6	(26.7, 81.1)	0.4858	30.6	(-33.9,74.1)
< 50 years	14	1	7.1	(1.3, 31.5)	24	12	50.0	(31.4, 68.6)	0.0089	42.9	(7.1,65.5)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	9	56.3	(33.2, 76.9)	0.0292	40.9	(4.0,69.8)
White	5	0	0.0	(0.0, 43.4)	17	8	47.1	(26.2, 69.0)	0.0995	47.1	(-8.9,72.7)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	19	9	47.4	(27.3, 68.3)	0.1895	47.4	(-7.3,71.6)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	8	57.1	(32.6, 78.6)	0.0322	41.8	(2.9,71.8)
BMI											
< 25 kg/m2	9	0	0.0		14	7	50.0				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		9	5	55.6				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		22	10	45.5				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.3 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.50	(1.78,59.83)	4.63	(1.21,55.31) (1.20,17.85)	
Sex					NC
Male	inf	(0.56, inf)	inf	(0.58, inf)	
Female	7.94	(1.43,59.99)	4.13	(1.12,40.60) (1.07,15.91)	
Age					0.3936
>= 50 years	3.75	(0.25,117.01)	2.22	(0.50,59.74) (0.37,13.38)	
< 50 years	13.00	(1.72,300.12)	7.00	(1.14,196.33) (1.02,48.25)	
Race					NC
Asian	7.07	(1.16,56.15)	3.66	(1.06,28.04) (0.95,14.05)	
White	inf	(1.17, inf)	inf	(0.81, inf)	
Region					NC
Europe + Africa + US	inf	(1.22, inf)	inf	(0.84, inf)	
Asia(ex Japan) + Japan	7.33	(1.14,59.66)	3.71	(1.12,30.47) (0.96,14.37)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.5.3 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	6	75.0				
No	11	1	9.1		19	8	42.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	21	12	57.1	(36.5, 75.5)	0.0075	48.8	(8.6,72.3)
=4	6	1	16.7	(3.0, 56.4)	12	5	41.7	(19.3, 68.0)	0.4438	25.0	(-28.1,62.9)
Baseline GPPGA score											
=3	15	2	13.3		27	15	55.6				
=4	3	0	0.0		6	2	33.3				
Baseline plaque psoriasis											
Yes	3	0	0.0		6	3	50.0				
No	15	2	13.3		27	14	51.9				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	13	5	38.5	(17.7, 64.5)	0.0525	38.5	(-0.4,68.4)
No	10	2	20.0	(5.7, 51.0)	20	12	60.0	(38.7, 78.1)	0.0751	40.0	(-1.9,68.5)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		32	17	53.1				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		30	15	50.0				

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Table 2.3.5.3 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4644
<4	14.67	(1.82,342.49)	6.86	(1.18,195.16) (1.01,46.43)	
=4	3.57	(0.32,100.84)	2.50	(0.50,65.50) (0.37,16.89)	
Baseline GPPGA score					
=3					
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.29, inf)	inf	(0.86, inf)	
No	6.00	(1.00,47.64)	3.00	(0.94,27.08) (0.83,10.90)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Table 2.3.5.3 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NR-IEI)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		25	14	56.0			
Mild	1	0	0.0		5	2	40.0			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

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Table 2.3.5.3 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 15 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 85 at baseline (EN-NR-IEI)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI)	Risk ratio (asymp 95% CI)	p-value**
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 2.3.5.4 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	9	50.0	(29.0, 71.0)	35	23	65.7	(49.2, 79.2)	0.3794	15.7	(-12.6,43.3)
Sex											
Male	3	2	66.7	(20.8, 93.9)	14	8	57.1	(32.6, 78.6)	1.0000	-9.5	(-56.4,52.2)
Female	15	7	46.7	(24.8, 69.9)	21	15	71.4	(50.0, 86.2)	0.1590	24.8	(-8.8,55.1)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	8	57.1	(32.6, 78.6)	24	18	75.0	(55.1, 88.0)	0.3466	17.9	(-13.4,49.0)
Race											
Asian	13	6	46.2	(23.2, 70.9)	16	9	56.3	(33.2, 76.9)	0.6372	10.1	(-27.1,45.6)
White	5	3	60.0	(23.1, 88.2)	19	14	73.7	(51.2, 88.2)	0.7314	13.7	(-28.7,60.8)
Region											
Europe + Africa + US	5	3	60.0	(23.1, 88.2)	21	15	71.4	(50.0, 86.2)	1.0000	11.4	(-29.9,58.8)
Asia(ex Japan) + Japan	13	6	46.2	(23.2, 70.9)	14	8	57.1	(32.6, 78.6)	0.6898	11.0	(-29.5,47.7)
BMI											
< 25 kg/m2	9	5	55.6	(26.7, 81.1)	15	9	60.0	(35.7, 80.2)	0.8961	4.4	(-36.1,45.2)
25 to < 30 kg/m2	6	4	66.7	(30.0, 90.3)	10	7	70.0	(39.7, 89.2)	1.0000	3.3	(-43.0,53.2)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	7	70.0	(39.7, 89.2)	0.0524	70.0	(-0.6,94.3)
Mutation status IL36RN											
Yes	2	1	50.0		5	5	100.0				
No	12	6	50.0		24	14	58.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 2.3.5.4 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.92	(0.58,6.24)	1.31	(0.81,2.76) (0.78,2.21)	
Sex					0.3019
Male	0.67	(0.02,10.87)	0.86	(0.37,7.04) (0.34,2.15)	
Female	2.86	(0.68,11.94)	1.53	(0.84,3.54) (0.84,2.80)	
Age					0.7349
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	2.25	(0.52,9.54)	1.31	(0.81,2.65) (0.79,2.18)	
Race					0.9887
Asian	1.50	(0.33,6.88)	1.22	(0.58,3.05) (0.59,2.53)	
White	1.87	(0.17,15.96)	1.23	(0.67,8.69) (0.57,2.64)	
Region					0.9425
Europe + Africa + US	1.67	(0.16,13.80)	1.19	(0.65,7.87) (0.55,2.56)	
Asia(ex Japan) + Japan	1.56	(0.32,7.52)	1.24	(0.53,2.94) (0.59,2.60)	
BMI					NC
< 25 kg/m2	1.20	(0.20,6.80)	1.08	(0.52,3.05) (0.53,2.21)	
25 to < 30 kg/m2	1.17	(0.10,11.39)	1.05	(0.49,3.04) (0.52,2.11)	
>= 30 kg/m2	inf	(1.26, inf)	inf	(0.90, inf)	
Mutation status IL36RN					
Yes					
No					

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Table 2.3.5.4 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	3	50.0	(18.8, 81.2)	8	7	87.5	(52.9, 97.8)	0.2159	37.5	(-17.9,79.2)
No	11	6	54.5	(28.0, 78.7)	21	12	57.1	(36.5, 75.5)	0.9486	2.6	(-33.2,38.7)
Baseline GPPGA pustulation subscore											
<4	12	4	33.3	(13.8, 60.9)	22	14	63.6	(43.0, 80.3)	0.1411	30.3	(-6.1,60.7)
=4	6	5	83.3	(43.6, 97.0)	13	9	69.2	(42.4, 87.3)	0.8189	-14.1	(-51.4,36.0)
Baseline GPPGA score											
=3	15	7	46.7	(24.8, 69.9)	28	20	71.4	(52.9, 84.7)	0.1412	24.8	(-6.8,53.7)
=4	3	2	66.7	(20.8, 93.9)	7	3	42.9	(15.8, 75.0)	0.8467	-23.8	(-76.0,47.1)
Baseline plaque psoriasis											
Yes	3	2	66.7		6	4	66.7				
No	15	7	46.7		29	19	65.5				
Background treatment prior to randomization											
Yes	8	3	37.5	(13.7, 69.4)	15	8	53.3	(30.1, 75.2)	0.7546	15.8	(-29.3,54.5)
No	10	6	60.0	(31.3, 83.2)	20	15	75.0	(53.1, 88.8)	0.4622	15.0	(-20.5,52.0)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	9	56.3		34	23	67.6				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	9	50.0		32	20	62.5				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.4 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.3456
Yes	7.00	(0.45,207.94)	1.75	(0.80,10.53) (0.75,4.06)	
No	1.11	(0.24,5.05)	1.05	(0.54,2.69) (0.54,2.02)	
Baseline GPPGA pustulation subscore					0.1028
<4	3.50	(0.77,16.66)	1.91	(0.86,8.02) (0.81,4.51)	
=4	0.45	(0.02,5.07)	0.83	(0.45,1.89) (0.50,1.38)	
Baseline GPPGA score					0.1948
=3	2.86	(0.74,10.87)	1.53	(0.89,3.96) (0.85,2.76)	
=4	0.38	(0.01,7.81)	0.64	(0.15,5.97) (0.20,2.07)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8273
Yes	1.90	(0.31,12.60)	1.42	(0.53,7.75) (0.52,3.91)	
No	2.00	(0.35,10.63)	1.25	(0.74,3.12) (0.71,2.20)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.4 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	9	56.3		26	20	76.9			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.4 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 1 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.5 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff.	Speso 900 mg IV SD vs Placebo (95% CI)
Overall	18	3	16.7	(5.8, 39.2)	35	20	57.1	(40.9, 72.0)	0.0067	40.5	(9.5,61.8)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	3	20.0	(7.0, 45.2)	21	13	61.9	(40.9, 79.2)	0.0200	41.9	(8.1,67.8)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	2	14.3	(4.0, 39.9)	24	15	62.5	(42.7, 78.8)	0.0069	48.2	(12.2,71.4)
Race											
Asian	13	3	23.1	(8.2, 50.3)	16	10	62.5	(38.6, 81.5)	0.0410	39.4	(1.5,69.1)
White	5	0	0.0	(0.0, 43.4)	19	10	52.6	(31.7, 72.7)	0.0449	52.6	(-7.3,75.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	11	52.4	(32.4, 71.7)	0.0768	52.4	(-6.1,75.1)
Asia(ex Japan) + Japan	13	3	23.1	(8.2, 50.3)	14	9	64.3	(38.8, 83.7)	0.0378	41.2	(2.0,72.6)
BMI											
< 25 kg/m2	9	1	11.1	(2.0, 43.5)	15	9	60.0	(35.7, 80.2)	0.0276	48.9	(3.6,76.6)
25 to < 30 kg/m2	6	2	33.3	(9.7, 70.0)	10	5	50.0	(23.7, 76.3)	0.7018	16.7	(-35.7,61.0)
>= 30 kg/m2	3	0	0.0	(0.0, 56.1)	10	6	60.0	(31.3, 83.2)	0.2112	60.0	(-13.6,90.5)
Mutation status IL36RN											
Yes	2	0	0.0		5	5	100.0				
No	12	2	16.7		24	11	45.8				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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inf = infinity. NC = not calculable

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Table 2.3.5.5 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	6.67	(1.66,32.22)	3.43	(1.11,22.47) (1.17,10.02)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	6.50	(1.37,34.65)	3.10	(1.12,22.60) (1.07,8.99)	
Age					0.4434
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	10.00	(1.85,73.97)	4.38	(1.21,45.03) (1.17,16.38)	
Race					NC
Asian	5.56	(1.04,32.17)	2.71	(1.04,11.86) (0.94,7.84)	
White	inf	(1.49, inf)	inf	(0.92, inf)	
Region					NC
Europe + Africa + US	inf	(1.51, inf)	inf	(0.94, inf)	
Asia(ex Japan) + Japan	6.00	(1.06,36.18)	2.79	(1.04,13.48) (0.96,8.09)	
BMI					NC
< 25 kg/m2	12.00	(1.27,295.27)	5.40	(1.12,151.26) (0.81,35.87)	
25 to < 30 kg/m2	2.00	(0.22,21.06)	1.50	(0.43,9.23) (0.41,5.45)	
>= 30 kg/m2	inf	(0.87, inf)	inf	(0.74, inf)	
Mutation status IL36RN					
Yes					
No					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.5 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7	(3.0, 56.4)	8	7	87.5	(52.9, 97.8)	0.0151	70.8	(12.6,96.0)
No	11	2	18.2	(5.1, 47.7)	21	9	42.9	(24.5, 63.5)	0.3134	24.7	(-12.2,53.2)
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	13	59.1	(38.7, 76.7)	0.0065	50.8	(13.3,73.5)
=4	6	2	33.3	(9.7, 70.0)	13	7	53.8	(29.1, 76.8)	0.4869	20.5	(-30.9,61.2)
Baseline GPPGA score											
=3	15	3	20.0	(7.0, 45.2)	28	17	60.7	(42.4, 76.4)	0.0168	40.7	(7.0,64.9)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	3	20.0		29	16	55.2				
Background treatment prior to randomization											
Yes	8	1	12.5	(2.2, 47.1)	15	6	40.0	(19.8, 64.3)	0.3175	27.5	(-15.9,59.1)
No	10	2	20.0	(5.7, 51.0)	20	14	70.0	(48.1, 85.5)	0.0131	50.0	(9.8,76.4)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	3	18.8		34	20	58.8				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	3	16.7		32	18	56.3				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.5 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					0.4864
Yes	35.00	(1.63,929.67)	5.25	(1.21,160.43) (0.86,32.02)	
No	3.38	(0.59,26.83)	2.36	(0.71,19.32) (0.61,9.07)	
Baseline GPPGA pustulation subscore					0.2025
<4	15.89	(1.99,368.92)	7.09	(1.18,204.04) (1.05,47.81)	
=4	2.33	(0.29,22.83)	1.62	(0.53,15.12) (0.47,5.57)	
Baseline GPPGA score					NC
=3	6.18	(1.41,31.42)	3.04	(1.08,17.77) (1.06,8.72)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.9396
Yes	4.67	(0.49,122.42)	3.20	(0.62,84.14) (0.46,22.16)	
No	9.33	(1.48,74.24)	3.50	(1.12,38.64) (0.98,12.49)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.5 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	3	18.8		26	17	65.4			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.5 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 4 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.6 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	(3.1, 32.8)	35	18	51.4	(35.6, 67.0)	0.0067	40.3	(9.6,60.7)
Sex											
Male	3	0	0.0	(0.0, 56.1)	14	7	50.0	(26.8, 73.2)	0.1596	50.0	(-19.1,77.0)
Female	15	2	13.3	(3.7, 37.9)	21	11	52.4	(32.4, 71.7)	0.0200	39.0	(5.0,64.6)
Age											
>= 50 years	4	1	25.0	(4.6, 69.9)	11	5	45.5	(21.3, 72.0)	0.6054	20.5	(-39.0,63.6)
< 50 years	14	1	7.1	(1.3, 31.5)	24	13	54.2	(35.1, 72.1)	0.0069	47.0	(12.2,69.2)
Race											
Asian	13	2	15.4	(4.3, 42.2)	16	10	62.5	(38.6, 81.5)	0.0115	47.1	(10.7,74.8)
White	5	0	0.0	(0.0, 43.4)	19	8	42.1	(23.1, 63.7)	0.1895	42.1	(-11.5,66.6)
Region											
Europe + Africa + US	5	0	0.0	(0.0, 43.4)	21	9	42.9	(24.5, 63.5)	0.1718	42.9	(-9.2,67.1)
Asia(ex Japan) + Japan	13	2	15.4	(4.3, 42.2)	14	9	64.3	(38.8, 83.7)	0.0112	48.9	(9.3,77.9)
BMI											
< 25 kg/m2	9	0	0.0		15	8	53.3				
25 to < 30 kg/m2	6	2	33.3		10	5	50.0				
>= 30 kg/m2	3	0	0.0		10	5	50.0				
Mutation status IL36RN											
Yes	2	0	0.0		5	4	80.0				
No	12	1	8.3		24	10	41.7				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.6 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.47	(1.80,59.33)	4.63	(1.21,52.13) (1.21,17.78)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	7.15	(1.31,53.78)	3.93	(1.12,38.68) (1.02,15.20)	
Age					0.2902
>= 50 years	2.50	(0.19,78.15)	1.82	(0.39,47.97) (0.30,11.18)	
< 50 years	15.36	(2.03,352.57)	7.58	(1.30,215.92) (1.11,51.94)	
Race					NC
Asian	9.17	(1.47,72.54)	4.06	(1.23,43.94) (1.07,15.36)	
White	inf	(0.98, inf)	inf	(0.77, inf)	
Region					NC
Europe + Africa + US	inf	(1.04, inf)	inf	(0.76, inf)	
Asia(ex Japan) + Japan	9.90	(1.50,80.39)	4.18	(1.22,30.59) (1.10,15.85)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					
Mutation status IL36RN					
Yes					
No					

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Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.6 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup	Placebo				Speso 900 mg IV SD				Speso 900 mg IV SD vs Placebo		
Category	N	n	%	(95% CI)	N	n	%	(95% CI)	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN after DNA resequencing											
Yes	6	1	16.7		8	6	75.0				
No	11	1	9.1		21	8	38.1				
Baseline GPPGA pustulation subscore											
<4	12	1	8.3	(1.5, 35.4)	22	12	54.5	(34.7, 73.1)	0.0148	46.2	(8.9,69.7)
=4	6	1	16.7	(3.0, 56.4)	13	6	46.2	(23.2, 70.9)	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score											
=3	15	2	13.3	(3.7, 37.9)	28	15	53.6	(35.8, 70.5)	0.0168	40.2	(7.0,63.4)
=4	3	0	0.0	(0.0, 56.1)	7	3	42.9	(15.8, 75.0)	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis											
Yes	3	0	0.0		6	4	66.7				
No	15	2	13.3		29	14	48.3				
Background treatment prior to randomization											
Yes	8	0	0.0	(0.0, 32.4)	15	5	33.3	(15.2, 58.3)	0.1229	33.3	(-6.9,61.6)
No	10	2	20.0	(5.7, 51.0)	20	13	65.0	(43.3, 81.9)	0.0340	45.0	(2.3,73.8)
Pain VAS score at baseline											
<= 40	2	0	0.0		1	0	0.0				
> 40	16	2	12.5		34	18	52.9				
Hepatic impairment at baseline											
Yes	0	0	na		0	0	na				
No	18	2	11.1		32	16	50.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.6 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.5302
<4	13.20	(1.67,308.36)	6.55	(1.18,185.27) (0.96,44.42)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					NC
=3	7.50	(1.48,54.43)	4.02	(1.08,41.33) (1.06,15.28)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(1.07, inf)	inf	(0.81, inf)	
No	7.43	(1.21,58.93)	3.25	(1.03,29.67) (0.90,11.70)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.6 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo (95% CI)	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD (95% CI)	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Renal impairment at baseline										
Normal	16	2	12.5		26	15	57.7			
Mild	1	0	0.0		6	2	33.3			
Moderate	0	0	na		1	0	0.0			
Severe	0	0	na		0	0	na			
ESRD	0	0	na		0	0	na			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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Table 2.3.5.6 Proportion of patients with EQ-5D(-5L) VAS score improvement of at least 10 from baseline overall and by subgroup at week 12 - RS, patients with EQ-5D(-5L) VAS score <= 90 at baseline (EN-NRI-IE)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Renal impairment at baseline			
Normal			
Mild			
Moderate			
Severe			
ESRD			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Confidence intervals (CIs) for proportions are Wilson confidence limits.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test.
**Q test for homogeneity of risk ratios (treatment by subgroup interaction).
inf = infinity. NC = not calculable

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1.2.4 Analysis including open-label spesolimab

Table 2.4.1 Proportion of patients for GPPGA pustulation subscore over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	GPPGA pustulation subscore: 0 n	%	(95% CI)	GPPGA pustulation subscore: 1 n	%	(95% CI)	GPPGA pustulation subscore: 2 n	%	(95% CI)
Baseline										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	4	26.7	(10.9, 52.0)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	0	0.0	(0.0, 9.9)	6	17.1	(8.1, 32.7)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)
Day 8										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	6	40.0	(19.8, 64.3)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	19	54.3	(38.2, 69.5)	1	2.9	(0.5, 14.5)	5	14.3	(6.3, 29.4)
Speso 900 mg IV SD only	23	19	82.6	(62.9, 93.0)	1	4.3	(0.8, 21.0)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	5	41.7	(19.3, 68.0)
Week 2										
Placebo + OL D8	15	11	73.3	(48.0, 89.1)	1	6.7	(1.2, 29.8)	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	23	65.7	(49.2, 79.2)	5	14.3	(6.3, 29.4)	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	18	78.3	(58.1, 90.3)	1	4.3	(0.8, 21.0)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	5	41.7	(19.3, 68.0)	4	33.3	(13.8, 60.9)	0	0.0	(0.0, 24.2)
Week 3										
Placebo + OL D8	15	10	66.7	(41.7, 84.8)	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	23	65.7	(49.2, 79.2)	5	14.3	(6.3, 29.4)	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	18	78.3	(58.1, 90.3)	1	4.3	(0.8, 21.0)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	5	41.7	(19.3, 68.0)	4	33.3	(13.8, 60.9)	0	0.0	(0.0, 24.2)
Week 4										
Placebo + OL D8	15	9	60.0	(35.7, 80.2)	1	6.7	(1.2, 29.8)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	23	65.7	(49.2, 79.2)	5	14.3	(6.3, 29.4)	1	2.9	(0.5, 14.5)
Speso 900 mg IV SD only	23	18	78.3	(58.1, 90.3)	1	4.3	(0.8, 21.0)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	5	41.7	(19.3, 68.0)	4	33.3	(13.8, 60.9)	1	8.3	(1.5, 35.4)
Week 8										
Placebo + OL D8	15	7	46.7	(24.8, 69.9)	3	20.0	(7.0, 45.2)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	22	62.9	(46.3, 76.8)	3	8.6	(3.0, 22.4)	1	2.9	(0.5, 14.5)
Speso 900 mg IV SD only	23	17	73.9	(53.5, 87.5)	1	4.3	(0.8, 21.0)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	5	41.7	(19.3, 68.0)	2	16.7	(4.7, 44.8)	1	8.3	(1.5, 35.4)
Week 12										
Placebo + OL D8	15	6	40.0	(19.8, 64.3)	3	20.0	(7.0, 45.2)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	21	60.0	(43.6, 74.4)	4	11.4	(4.5, 26.0)	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	15	65.2	(44.9, 81.2)	3	13.0	(4.5, 32.1)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	6	50.0	(25.4, 74.6)	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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Table 2.4.1 Proportion of patients for GPPGA pustulation subscore over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	GPPGA pustulation subscore: 3 n	%	(95% CI)	GPPGA pustulation subscore: 4 n	%	(95% CI)	Escape/rescue use: 0 n	%	(95% CI)
Baseline										
Placebo + OL D8	15	7	46.7	(24.8, 69.9)	4	26.7	(10.9, 52.0)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	16	45.7	(30.5, 61.8)	13	37.1	(23.2, 53.7)	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	12	52.2	(33.0, 70.8)	7	30.4	(15.6, 50.9)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	4	33.3	(13.8, 60.9)	6	50.0	(25.4, 74.6)	0	0.0	(0.0, 24.2)
Day 8										
Placebo + OL D8	15	6	40.0	(19.8, 64.3)	3	20.0	(7.0, 45.2)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	4	11.4	(4.5, 26.0)	3	8.6	(3.0, 22.4)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	4	33.3	(13.8, 60.9)	3	25.0	(8.9, 53.2)	0	0.0	(0.0, 24.2)
Week 2										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	2	5.7	(1.6, 18.6)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)	0	0.0	(0.0, 24.2)
Week 3										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)	1	2.9	(0.5, 14.5)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)
Week 4										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	1	2.9	(0.5, 14.5)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)
Week 8										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	4	26.7	(10.9, 52.0)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)	0	0.0	(0.0, 9.9)	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)
Week 12										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	0	0.0	(0.0, 9.9)	6	17.1	(8.1, 32.7)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	3	25.0	(8.9, 53.2)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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Table 2.4.1 Proportion of patients for GPPGA pustulation subscore over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	Escape/rescue use: >=1 or missing data n	%	(95% CI)
Baseline				
Placebo + OL D8	15	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)
Day 8				
Placebo + OL D8	15	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)
Week 2				
Placebo + OL D8	15	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)
Week 3				
Placebo + OL D8	15	4	26.7	(10.9, 52.0)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)
Week 4				
Placebo + OL D8	15	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)
Week 8				
Placebo + OL D8	15	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	2	16.7	(4.7, 44.8)
Week 12				
Placebo + OL D8	15	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	2	16.7	(4.7, 44.8)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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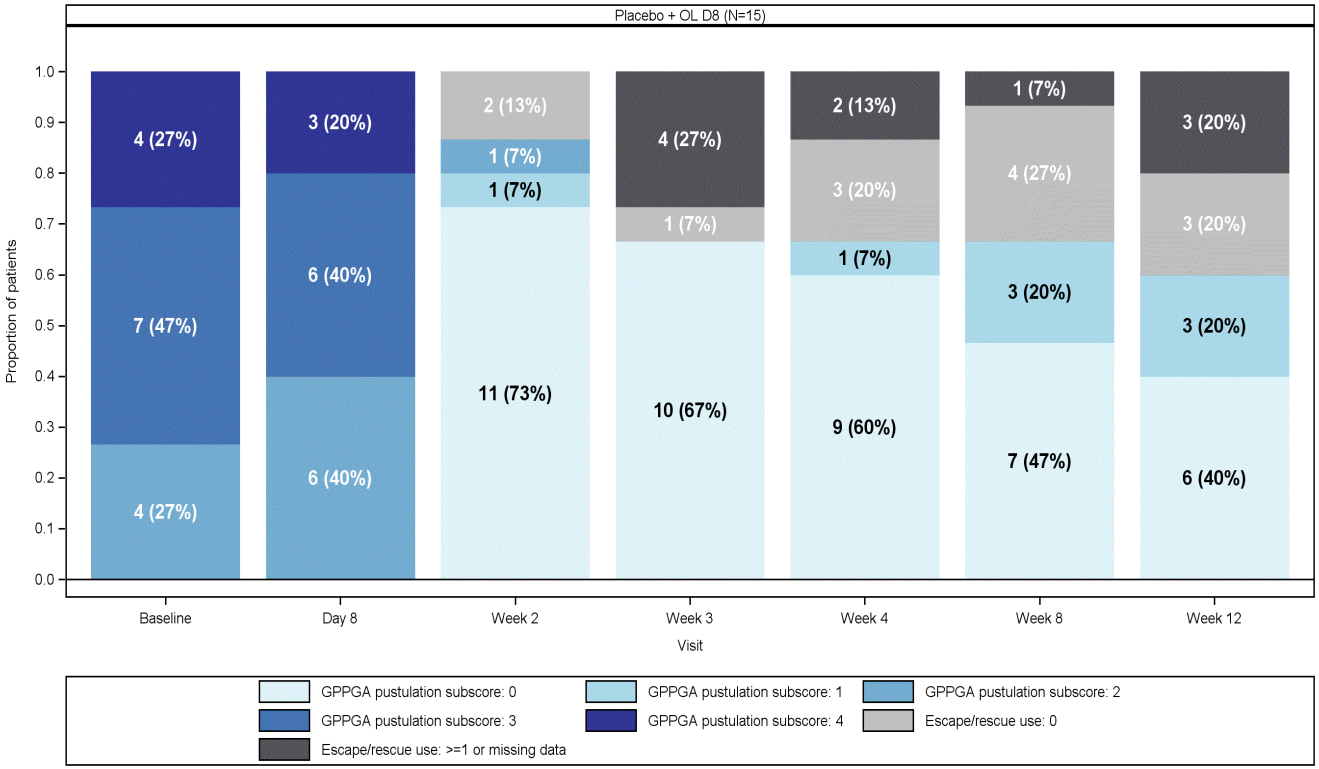

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.2 GPPGA pustulation subscore over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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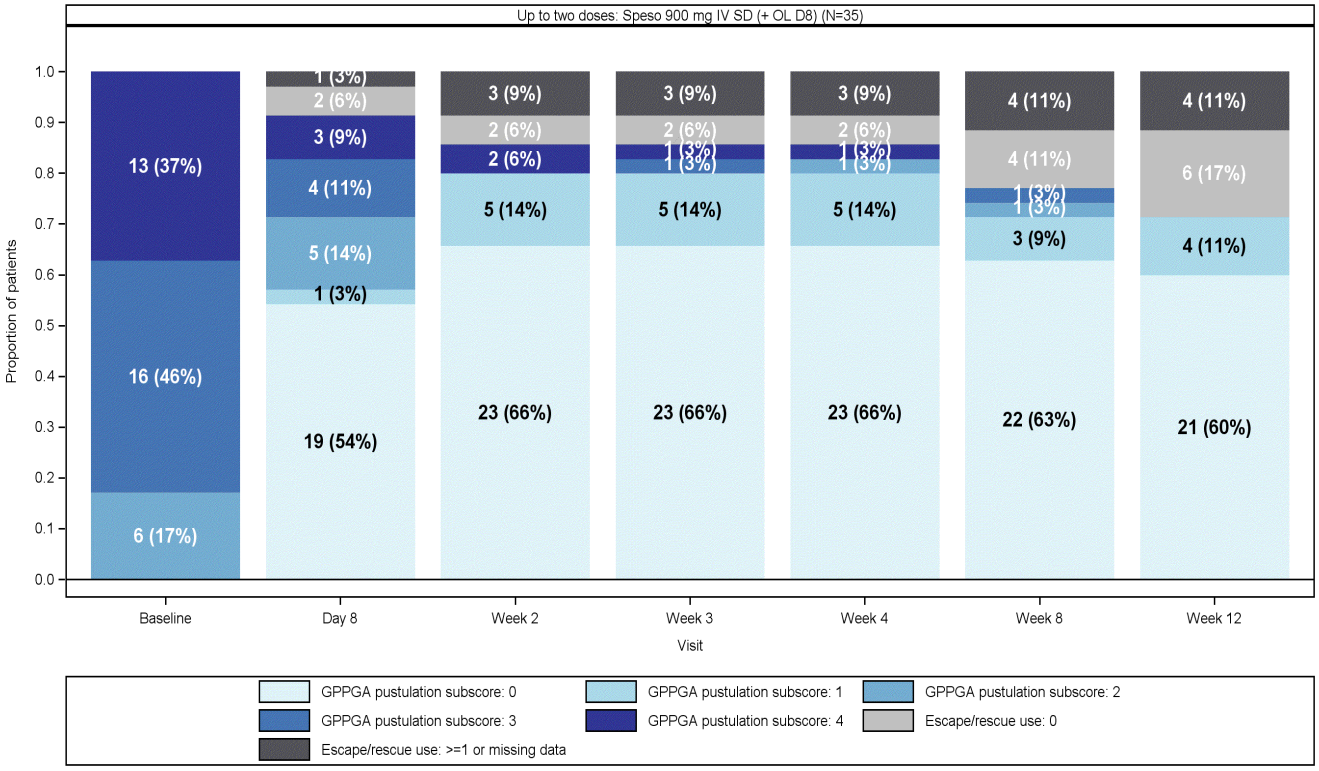

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.2 GPPGA pustulation subscore over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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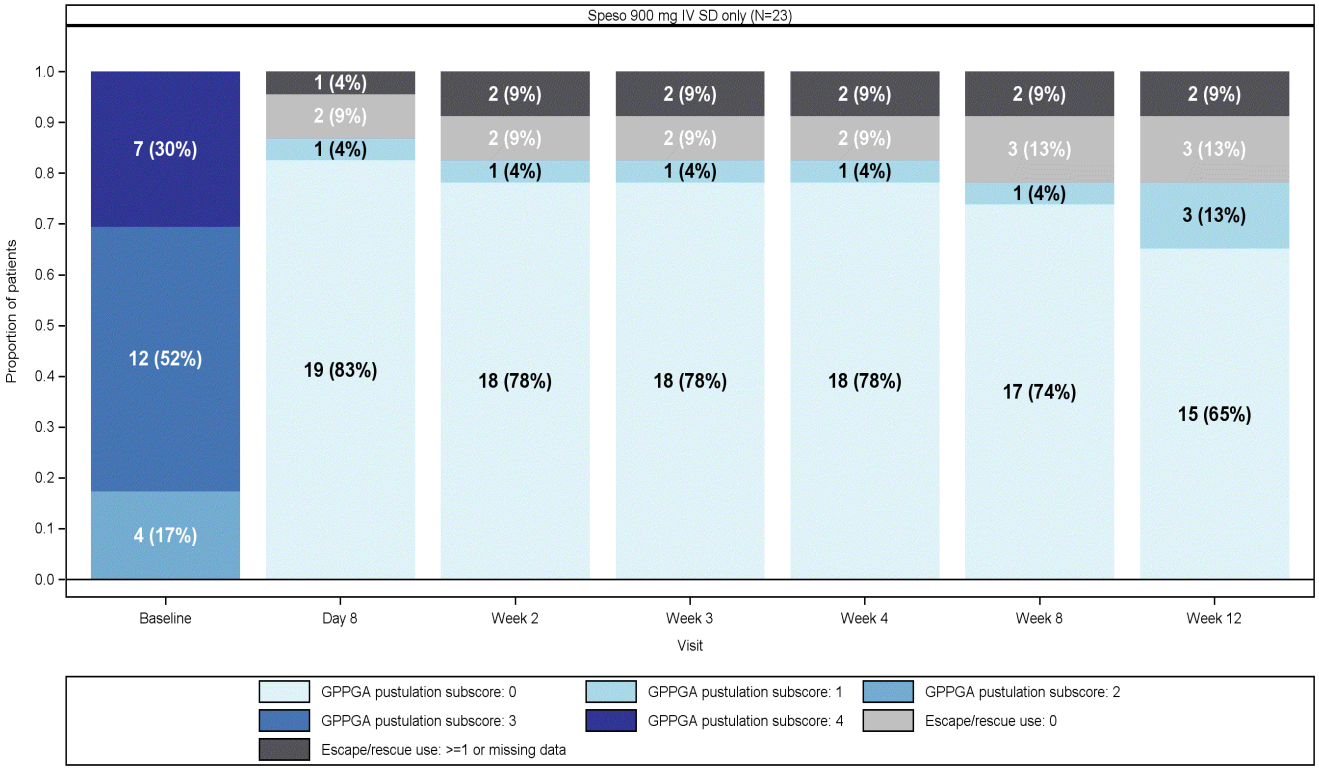

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.2 GPPGA pustulation subscore over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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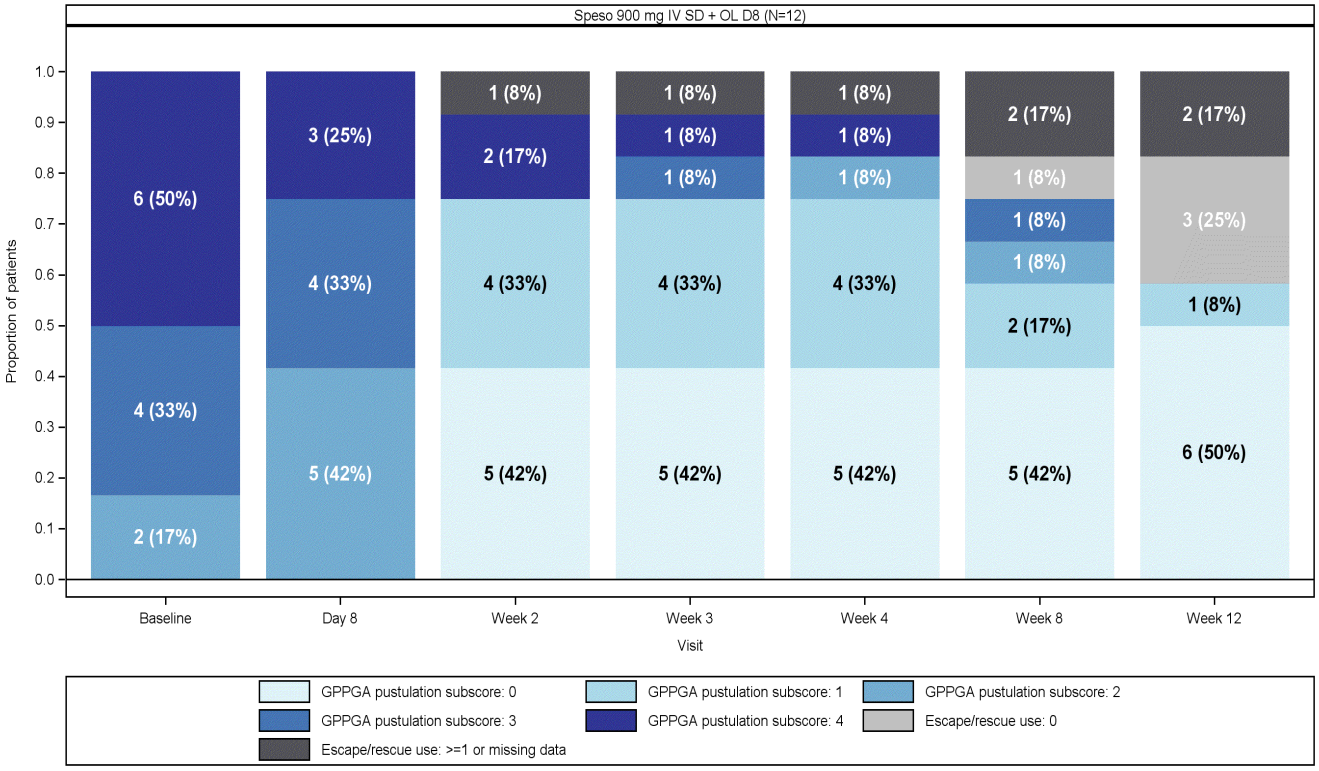

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.2 GPPGA pustulation subscore over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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Table 2.4.3 Proportion of patients for GPPGA total score over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	GPPGA total score: 0 n	%	(95% CI)	GPPGA total score: 1 n	%	(95% CI)	GPPGA total score: 2 n	%	(95% CI)
Baseline										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	0	0.0	(0.0, 9.9)	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)
Day 8										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	15	42.9	(28.0, 59.1)	7	20.0	(10.0, 35.9)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	15	65.2	(44.9, 81.2)	5	21.7	(9.7, 41.9)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)
Week 2										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	8	53.3	(30.1, 75.2)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	18	51.4	(35.6, 67.0)	10	28.6	(16.3, 45.1)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	16	69.6	(49.1, 84.4)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)	7	58.3	(32.0, 80.7)
Week 3										
Placebo + OL D8	15	1	6.7	(1.2, 29.8)	6	40.0	(19.8, 64.3)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)	18	51.4	(35.6, 67.0)	9	25.7	(14.2, 42.1)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)	14	60.9	(40.8, 77.8)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	4	33.3	(13.8, 60.9)	5	41.7	(19.3, 68.0)
Week 4										
Placebo + OL D8	15	1	6.7	(1.2, 29.8)	6	40.0	(19.8, 64.3)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)	20	57.1	(40.9, 72.0)	6	17.1	(8.1, 32.7)
Speso 900 mg IV SD only	23	3	13.0	(4.5, 32.1)	14	60.9	(40.8, 77.8)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	6	50.0	(25.4, 74.6)	4	33.3	(13.8, 60.9)
Week 8										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	10	66.7	(41.7, 84.8)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	5	14.3	(6.3, 29.4)	16	45.7	(30.5, 61.8)	5	14.3	(6.3, 29.4)
Speso 900 mg IV SD only	23	5	21.7	(9.7, 41.9)	11	47.8	(29.2, 67.0)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	5	41.7	(19.3, 68.0)	3	25.0	(8.9, 53.2)
Week 12										
Placebo + OL D8	15	2	13.3	(3.7, 37.9)	6	40.0	(19.8, 64.3)	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	4	11.4	(4.5, 26.0)	17	48.6	(33.0, 64.4)	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	4	17.4	(7.0, 37.1)	10	43.5	(25.6, 63.2)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	7	58.3	(32.0, 80.7)	0	0.0	(0.0, 24.2)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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Table 2.4.3 Proportion of patients for GPPGA total score over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	GPPGA total score: 3 n	%	(95% CI)	GPPGA total score: 4 n	%	(95% CI)	Escape/rescue use: 0/1 n	%	(95% CI)
Baseline										
Placebo + OL D8	15	12	80.0	(54.8, 93.0)	3	20.0	(7.0, 45.2)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	28	80.0	(64.1, 90.0)	7	20.0	(10.0, 35.9)	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	20	87.0	(67.9, 95.5)	3	13.0	(4.5, 32.1)	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	8	66.7	(39.1, 86.2)	4	33.3	(13.8, 60.9)	0	0.0	(0.0, 24.2)
Day 8										
Placebo + OL D8	15	12	80.0	(54.8, 93.0)	1	6.7	(1.2, 29.8)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	6	17.1	(8.1, 32.7)	4	11.4	(4.5, 26.0)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	6	50.0	(25.4, 74.6)	4	33.3	(13.8, 60.9)	0	0.0	(0.0, 24.2)
Week 2										
Placebo + OL D8	15	2	13.3	(3.7, 37.9)	0	0.0	(0.0, 20.4)	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	2	5.7	(1.6, 18.6)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)	0	0.0	(0.0, 24.2)
Week 3										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)	1	2.9	(0.5, 14.5)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)
Week 4										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)	0	0.0	(0.0, 9.9)	2	5.7	(1.6, 18.6)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)
Week 8										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	4	26.7	(10.9, 52.0)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)	0	0.0	(0.0, 9.9)	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)
Week 12										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	0	0.0	(0.0, 9.9)	5	14.3	(6.3, 29.4)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	0	0.0	(0.0, 14.3)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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Table 2.4.3 Proportion of patients for GPPGA total score over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	Escape/rescue use: >1 or missing data n	%	(95% CI)
Baseline				
Placebo + OL D8	15	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)
Day 8				
Placebo + OL D8	15	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	1	2.9	(0.5, 14.5)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)
Week 2				
Placebo + OL D8	15	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)
Week 3				
Placebo + OL D8	15	4	26.7	(10.9, 52.0)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)
Week 4				
Placebo + OL D8	15	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)
Week 8				
Placebo + OL D8	15	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	2	16.7	(4.7, 44.8)
Week 12				
Placebo + OL D8	15	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	5	14.3	(6.3, 29.4)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)
Speso 900 mg IV SD + OL D8	12	4	33.3	(13.8, 60.9)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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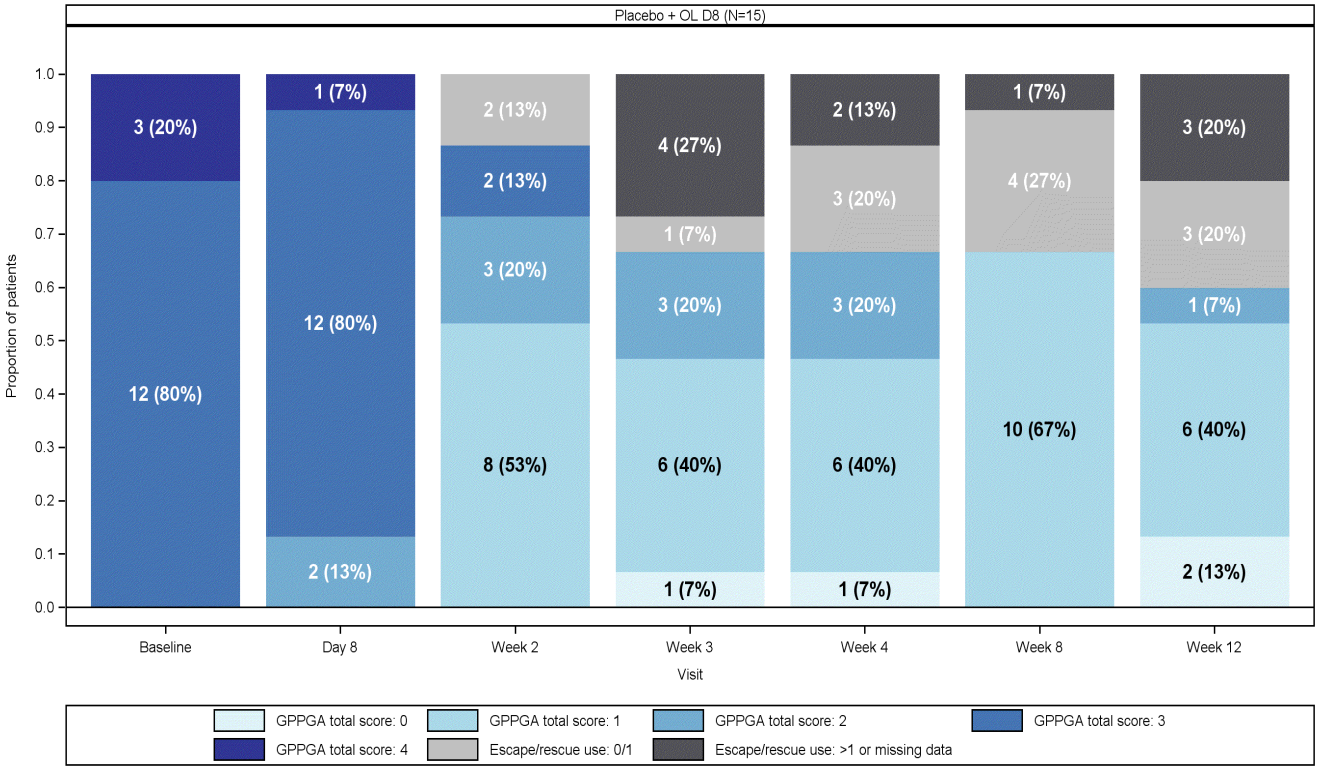

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.4 GPPGA total score over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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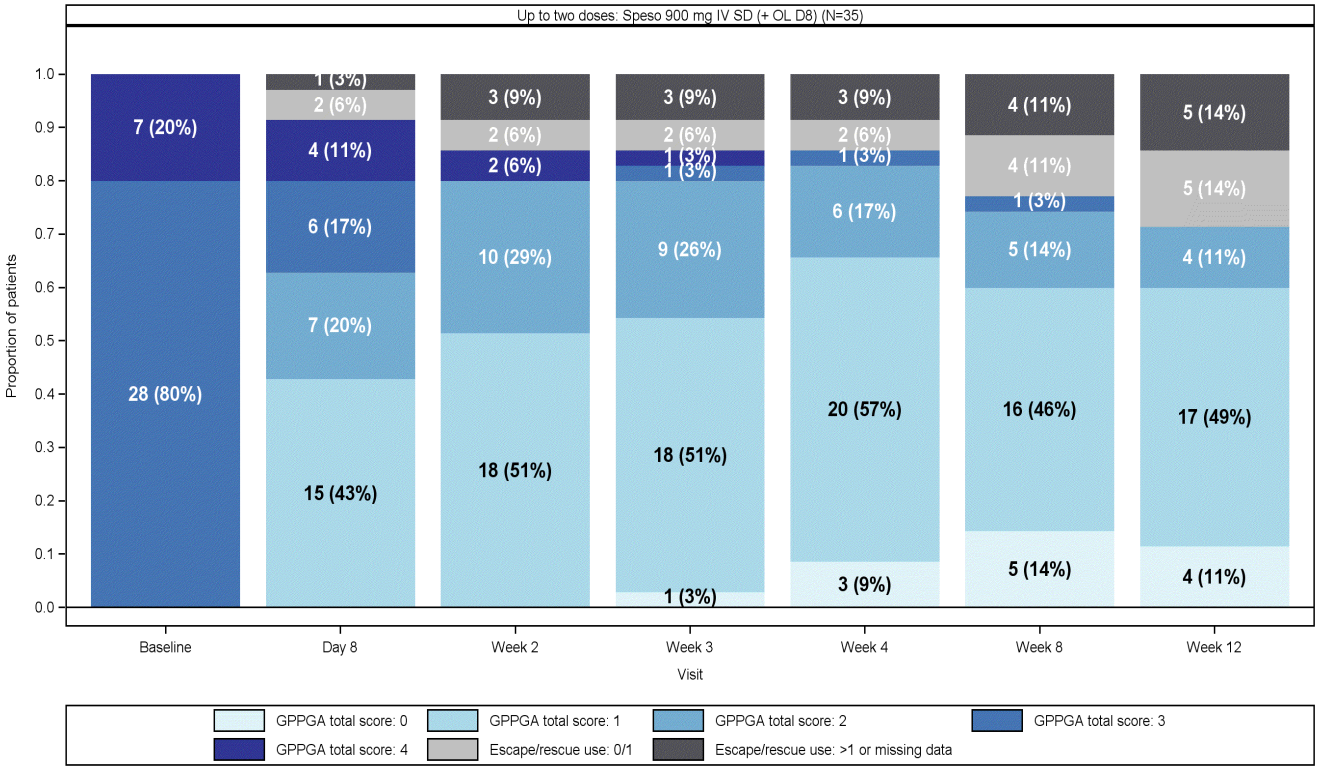

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.4 GPPGA total score over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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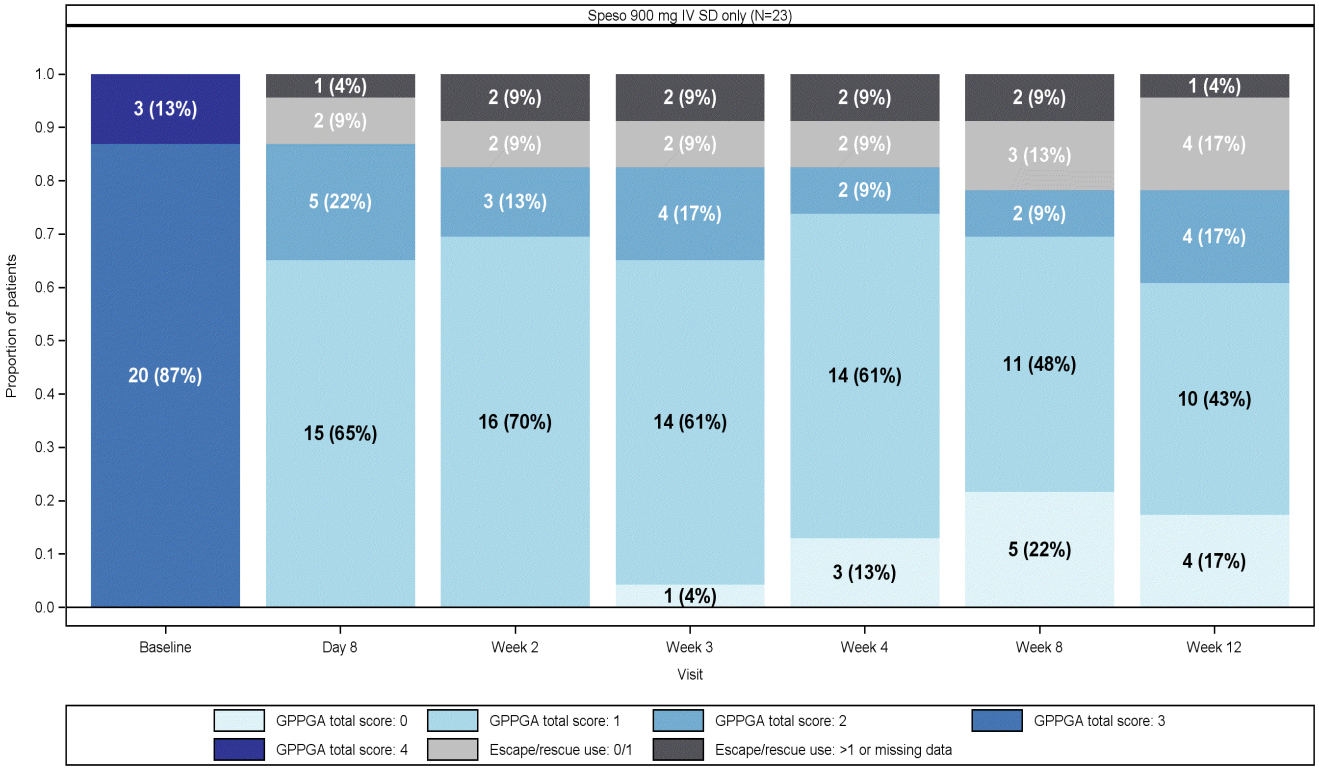

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.4 GPPGA total score over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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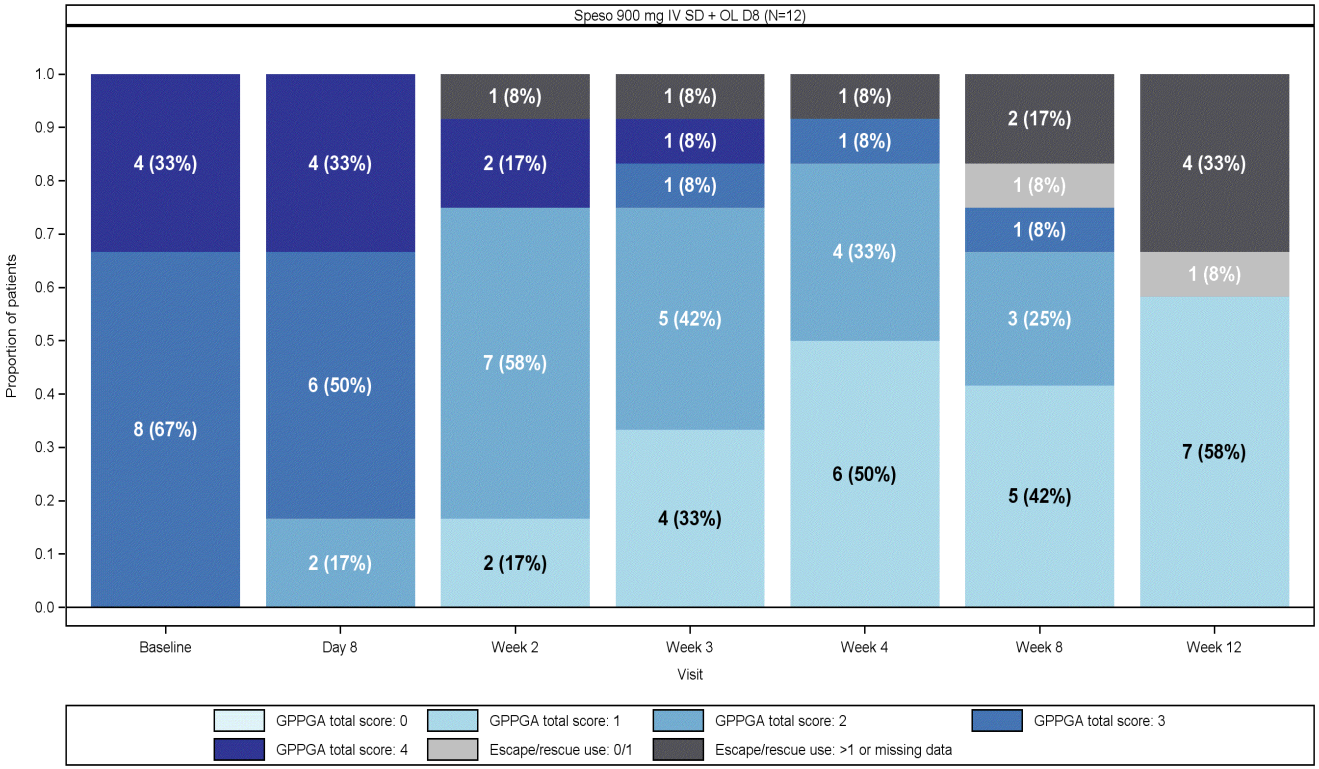

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.4 GPPGA total score over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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Table 2.4.5 Proportion of patients for GPPASI decrease over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	Decrease >=90% n	%	(95% CI)	Decrease >=75% - <90% n	%	(95% CI)	Decrease >=50% - <75% n	%	(95% CI)
Day 8										
Placebo + OL D8	15	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	4	11.4	(4.5, 26.0)	11	31.4	(18.6, 48.0)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	4	17.4	(7.0, 37.1)	11	47.8	(29.2, 67.0)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)
Week 2										
Placebo + OL D8	15	1	6.7	(1.2, 29.8)	3	20.0	(7.0, 45.2)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	4	11.4	(4.5, 26.0)	9	25.7	(14.2, 42.1)	7	20.0	(10.0, 35.9)
Speso 900 mg IV SD only	23	4	17.4	(7.0, 37.1)	8	34.8	(18.8, 55.1)	6	26.1	(12.5, 46.5)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)	1	8.3	(1.5, 35.4)
Week 3										
Placebo + OL D8	15	1	6.7	(1.2, 29.8)	5	33.3	(15.2, 58.3)	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	6	17.1	(8.1, 32.7)	10	28.6	(16.3, 45.1)	8	22.9	(12.1, 39.0)
Speso 900 mg IV SD only	23	6	26.1	(12.5, 46.5)	8	34.8	(18.8, 55.1)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)	4	33.3	(13.8, 60.9)
Week 4										
Placebo + OL D8	15	2	13.3	(3.7, 37.9)	4	26.7	(10.9, 52.0)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	8	22.9	(12.1, 39.0)	10	28.6	(16.3, 45.1)	9	25.7	(14.2, 42.1)
Speso 900 mg IV SD only	23	8	34.8	(18.8, 55.1)	8	34.8	(18.8, 55.1)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	2	16.7	(4.7, 44.8)	6	50.0	(25.4, 74.6)
Week 8										
Placebo + OL D8	15	8	53.3	(30.1, 75.2)	1	6.7	(1.2, 29.8)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	11	31.4	(18.6, 48.0)	10	28.6	(16.3, 45.1)	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	11	47.8	(29.2, 67.0)	5	21.7	(9.7, 41.9)	1	4.3	(0.8, 21.0)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	5	41.7	(19.3, 68.0)	3	25.0	(8.9, 53.2)
Week 12										
Placebo + OL D8	15	6	40.0	(19.8, 64.3)	1	6.7	(1.2, 29.8)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	12	34.3	(20.8, 50.8)	8	22.9	(12.1, 39.0)	5	14.3	(6.3, 29.4)
Speso 900 mg IV SD only	23	10	43.5	(25.6, 63.2)	4	17.4	(7.0, 37.1)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	2	16.7	(4.7, 44.8)	4	33.3	(13.8, 60.9)	1	8.3	(1.5, 35.4)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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Table 2.4.5 Proportion of patients for GPPASI decrease over time by visit and treatment - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

Visit / Treatment	N	Decrease <50% n	%	(95% CI)	Escape/rescue use: decrease >=75% n	%	(95% CI)	Escape/rescue use: decrease <75% or missing data n	%	(95% CI)
Day 8										
Placebo + OL D8	15	12	80.0	(54.8, 93.0)	0	0.0	(0.0, 20.4)	0	0.0	(0.0, 20.4)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	17	48.6	(33.0, 64.4)	0	0.0	(0.0, 9.9)	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	5	21.7	(9.7, 41.9)	0	0.0	(0.0, 14.3)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	12	100.0	(75.8, 100.0)	0	0.0	(0.0, 24.2)	0	0.0	(0.0, 24.2)
Week 2										
Placebo + OL D8	15	6	40.0	(19.8, 64.3)	0	0.0	(0.0, 20.4)	2	13.3	(3.7, 37.9)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	10	28.6	(16.3, 45.1)	1	2.9	(0.5, 14.5)	4	11.4	(4.5, 26.0)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)	1	4.3	(0.8, 21.0)	3	13.0	(4.5, 32.1)
Speso 900 mg IV SD + OL D8	12	9	75.0	(46.8, 91.1)	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)
Week 3										
Placebo + OL D8	15	2	13.3	(3.7, 37.9)	0	0.0	(0.0, 20.4)	5	33.3	(15.2, 58.3)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	6	17.1	(8.1, 32.7)	2	5.7	(1.6, 18.6)	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)	2	8.7	(2.4, 26.8)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	5	41.7	(19.3, 68.0)	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)
Week 4										
Placebo + OL D8	15	1	6.7	(1.2, 29.8)	2	13.3	(3.7, 37.9)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	3	8.6	(3.0, 22.4)	2	5.7	(1.6, 18.6)	3	8.6	(3.0, 22.4)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	2	8.7	(2.4, 26.8)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	3	25.0	(8.9, 53.2)	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)
Week 8										
Placebo + OL D8	15	1	6.7	(1.2, 29.8)	4	26.7	(10.9, 52.0)	1	6.7	(1.2, 29.8)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	2	5.7	(1.6, 18.6)	2	5.7	(1.6, 18.6)	6	17.1	(8.1, 32.7)
Speso 900 mg IV SD only	23	1	4.3	(0.8, 21.0)	1	4.3	(0.8, 21.0)	4	17.4	(7.0, 37.1)
Speso 900 mg IV SD + OL D8	12	1	8.3	(1.5, 35.4)	1	8.3	(1.5, 35.4)	2	16.7	(4.7, 44.8)
Week 12										
Placebo + OL D8	15	2	13.3	(3.7, 37.9)	3	20.0	(7.0, 45.2)	3	20.0	(7.0, 45.2)
Up to two doses: Speso 900 mg IV SD (+ OL D8)	35	0	0.0	(0.0, 9.9)	4	11.4	(4.5, 26.0)	6	17.1	(8.1, 32.7)
Speso 900 mg IV SD only	23	0	0.0	(0.0, 14.3)	3	13.0	(4.5, 32.1)	2	8.7	(2.4, 26.8)
Speso 900 mg IV SD + OL D8	12	0	0.0	(0.0, 24.2)	1	8.3	(1.5, 35.4)	4	33.3	(13.8, 60.9)

N is the number of patients in the respective treatment group. n is the number of patients with an event in the respective treatment group and endpoint category. Confidence intervals (CIs) for proportions are Wilson confidence limits.

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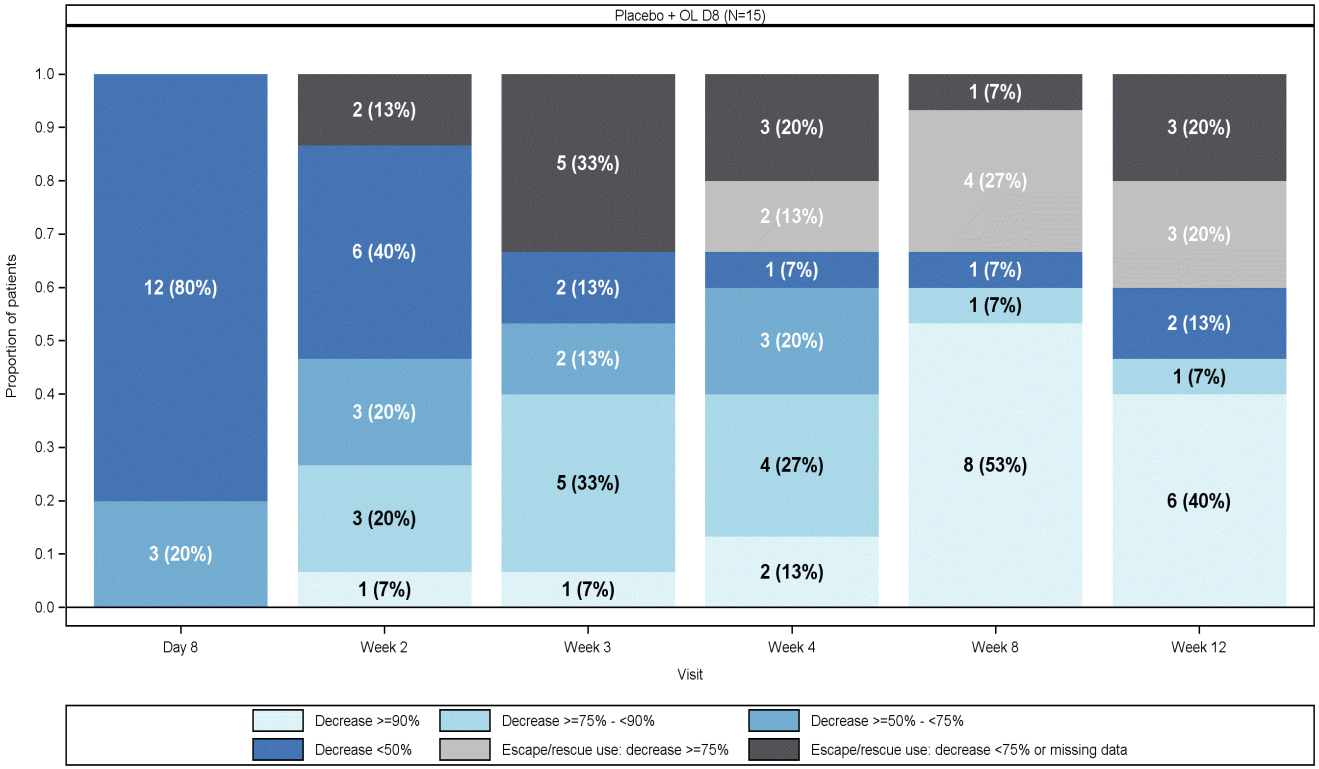

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.6 GPPASI decrease over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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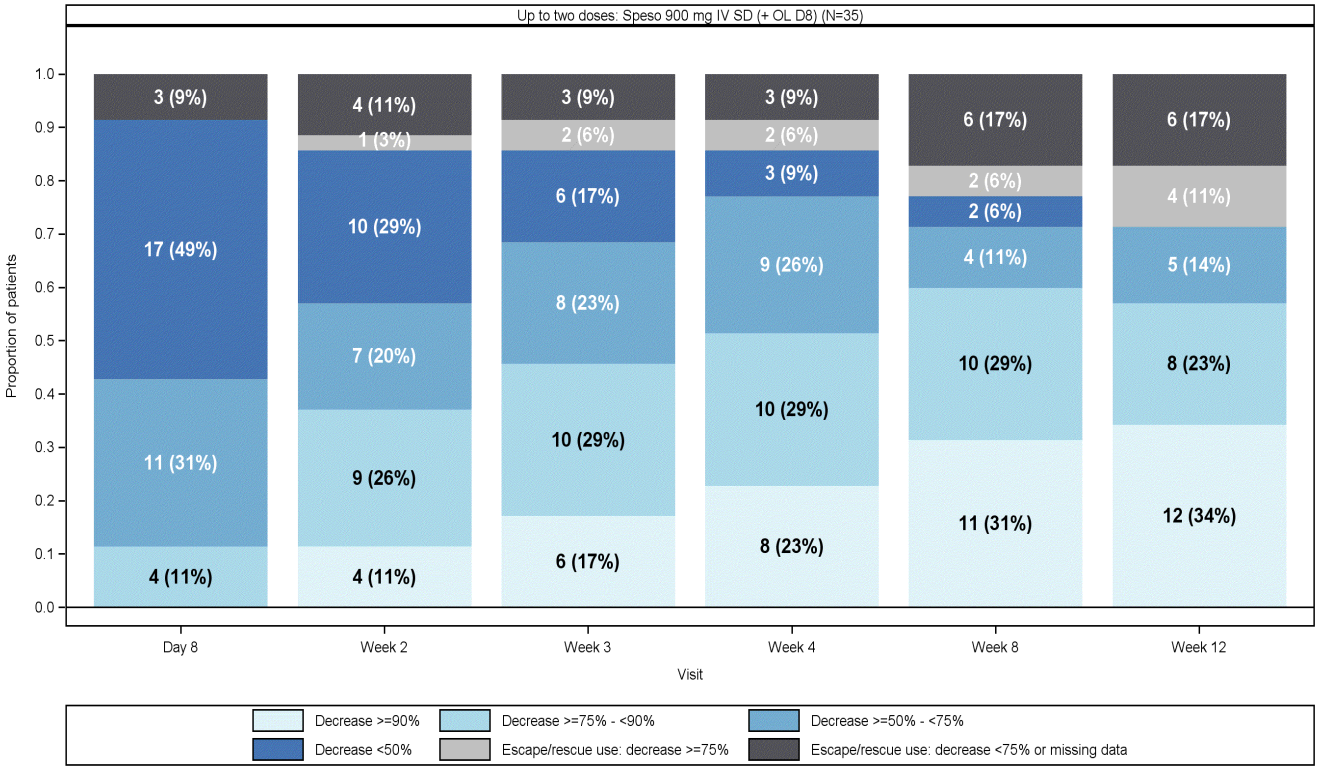

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.6 GPPASI decrease over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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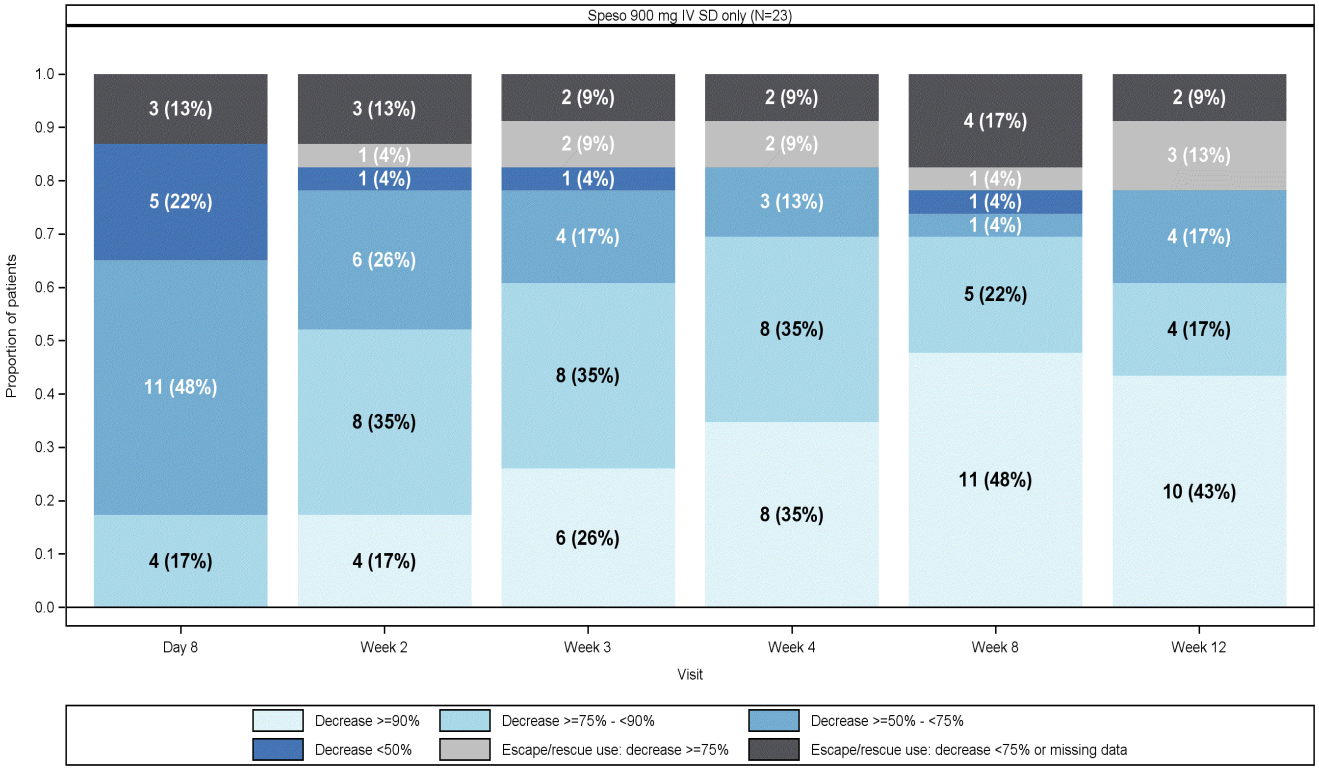

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.6 GPPASI decrease over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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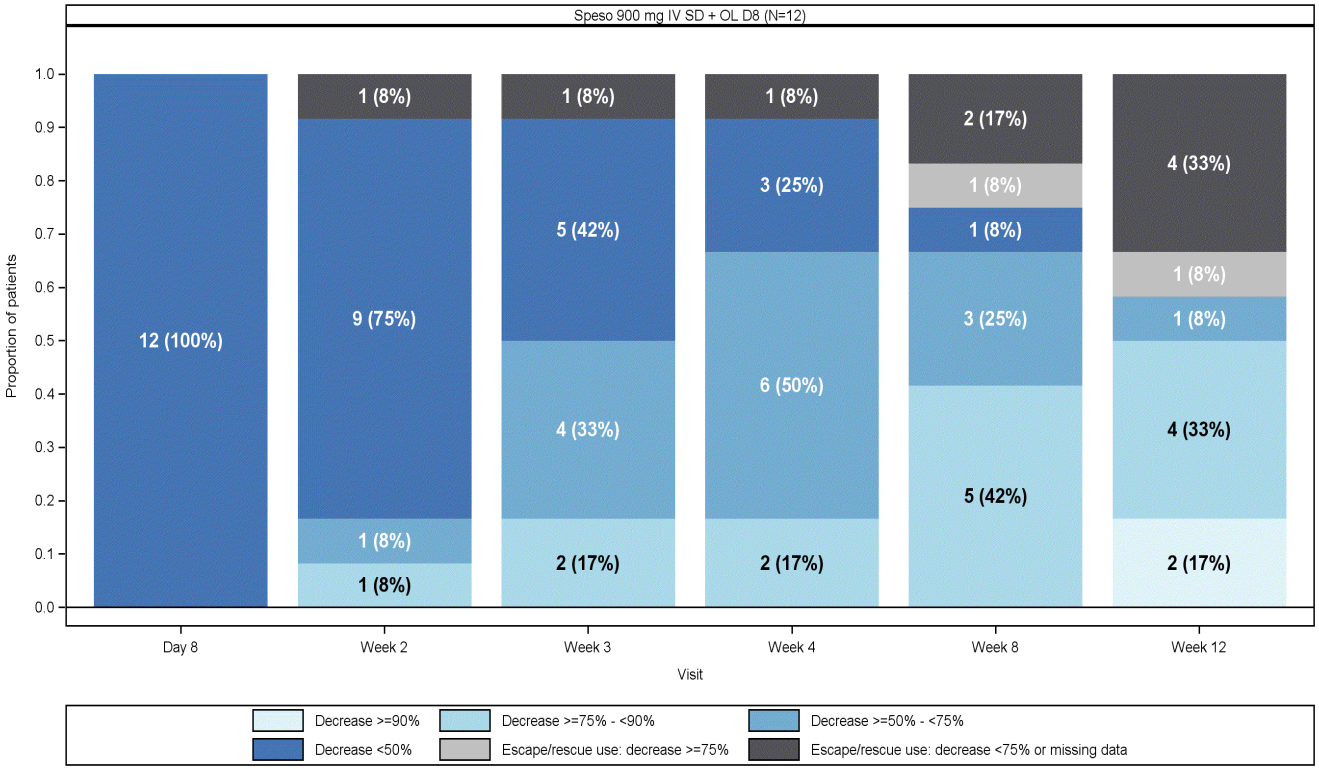

* escape/rescue use includes all patients with escape medication user or rescue treatment with spesolimab prior to each specific timepoint, together with one patient who was early discontinued before day 8 without escape or rescue use.
In addition, one patient with missing value at week 3 but with observed values at neighboring visits, i.e. week 2 and 4, was imputed with worst value from neighboring visits.

Figure 2.4.6 GPPASI decrease over time - RS (EN-ID8-NRI, in case of escape/rescue medication: OC-IR)

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1.2.5 Historical comparision

Table 2.5.1 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

Type of flare / Used timepoint of the category for 'time to be completely clear from pustules' pre Speso	Pre Speso N	Pre Speso n	Pre Speso %	Pre Speso Median [days]	Pre Speso (95% CI)	Post Speso N	Post Speso n	Post Speso %	Post Speso Median [days]	Post Speso (95% CI)	Post vs pre Speso HR*	Post vs pre Speso (95% CI)	Post vs pre Speso p-value
Typical flare													
Mid point	29	29	100.0	11.0	(11.00,25.00)	51	48	94.1	8.0	(6.00,9.00)	1.95	(1.18,3.21)	0.0088
Left point	29	29	100.0	8.0	(8.00,22.00)	51	48	94.1	8.0	(6.00,9.00)	1.19	(0.74,1.91)	0.4685
Right point	29	29	100.0	14.0	(14.00,28.00)	51	48	94.1	8.0	(6.00,9.00)	2.18	(1.31,3.62)	0.0027
Most severe flare													
Mid point	28	28	100.0	25.0	(NC.,NC.)	51	48	94.1	8.0	(6.00,9.00)	3.79	(2.12,6.79)	<0.0001
Left point	28	28	100.0	22.0	(NC.,NC.)	51	48	94.1	8.0	(6.00,9.00)	2.26	(1.32,3.87)	0.0030
Right point	28	28	100.0	28.0	(NC.,NC.)	51	48	94.1	8.0	(6.00,9.00)	4.36	(2.40,7.94)	<0.0001

NC. = Not calculated.

N is the number of patients in the respective group. n is the number of patients with an event in the respective group.
* Based on a Cox regression model with treatment and frailty term for patient.
Patients without a response prior to end of study are considered as non-responders and are censored at the day of end of study.

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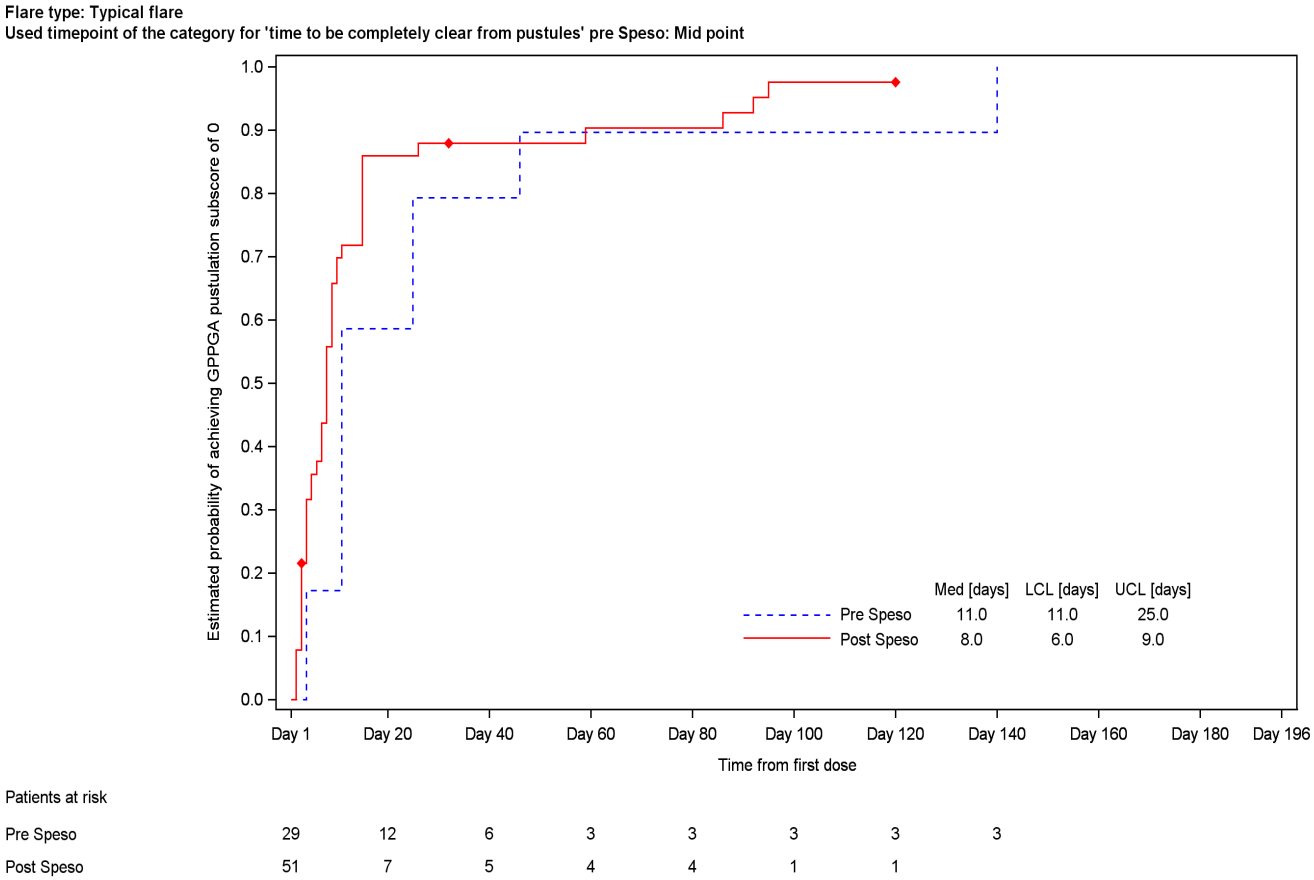

Figure 2.5.2 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

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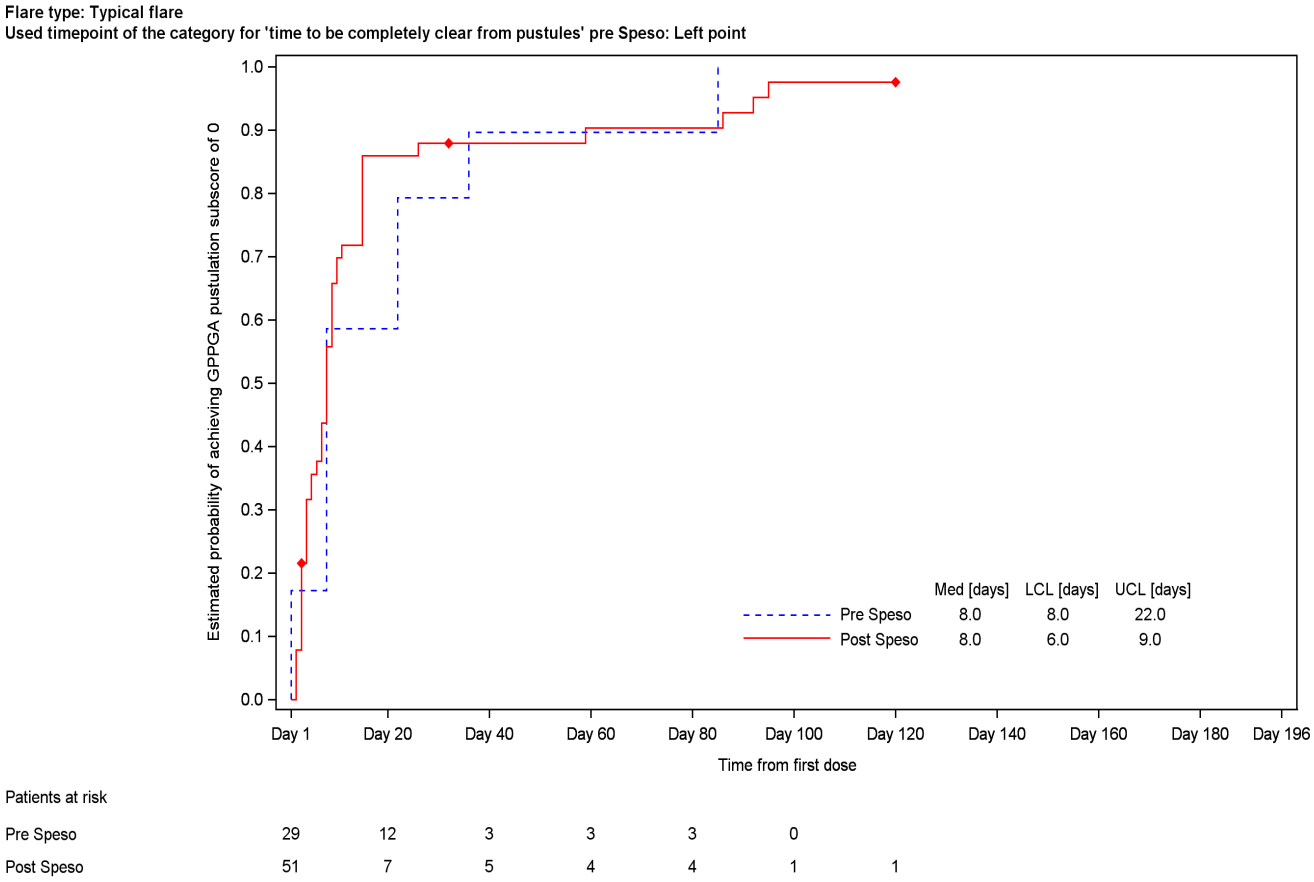

Figure 2.5.2 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

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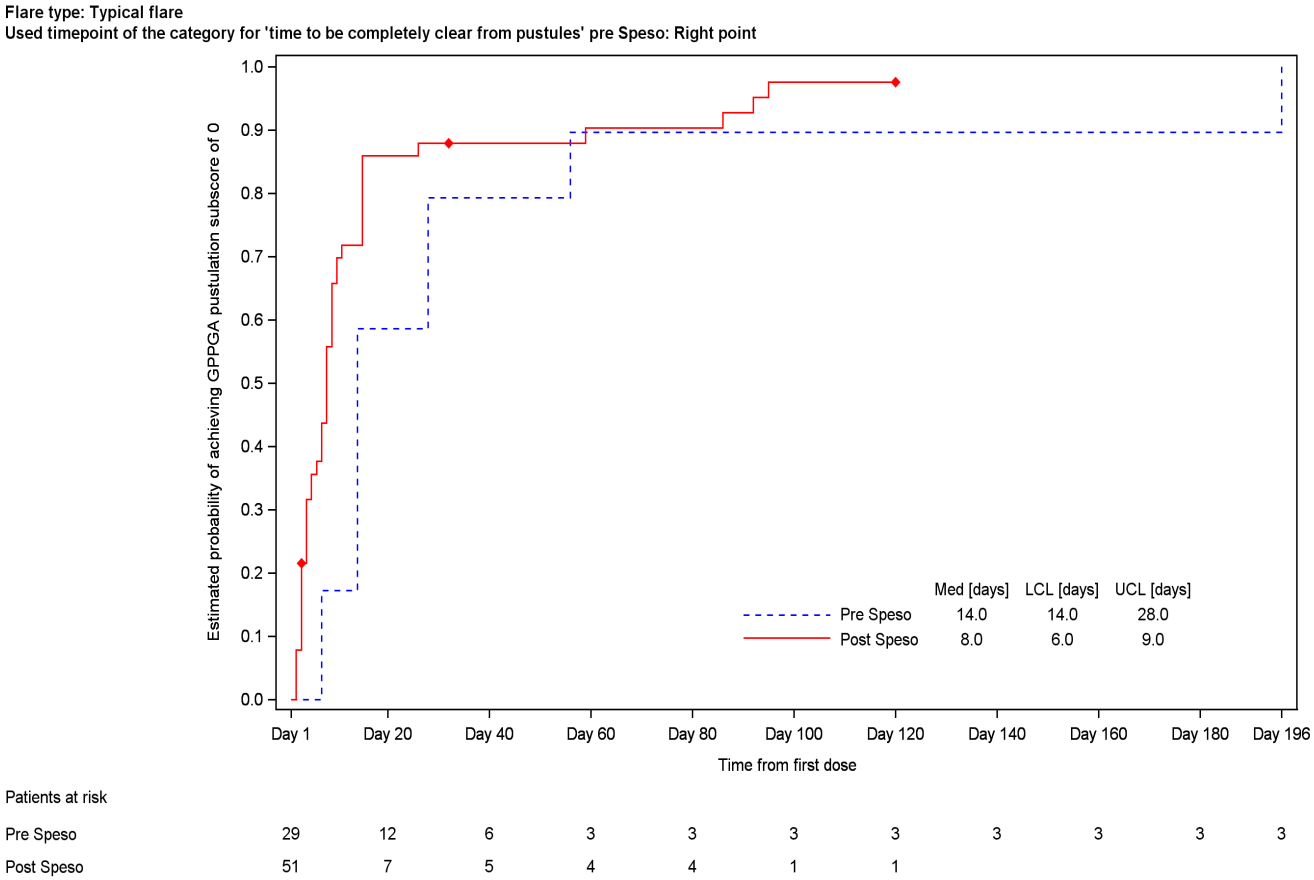

Figure 2.5.2 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

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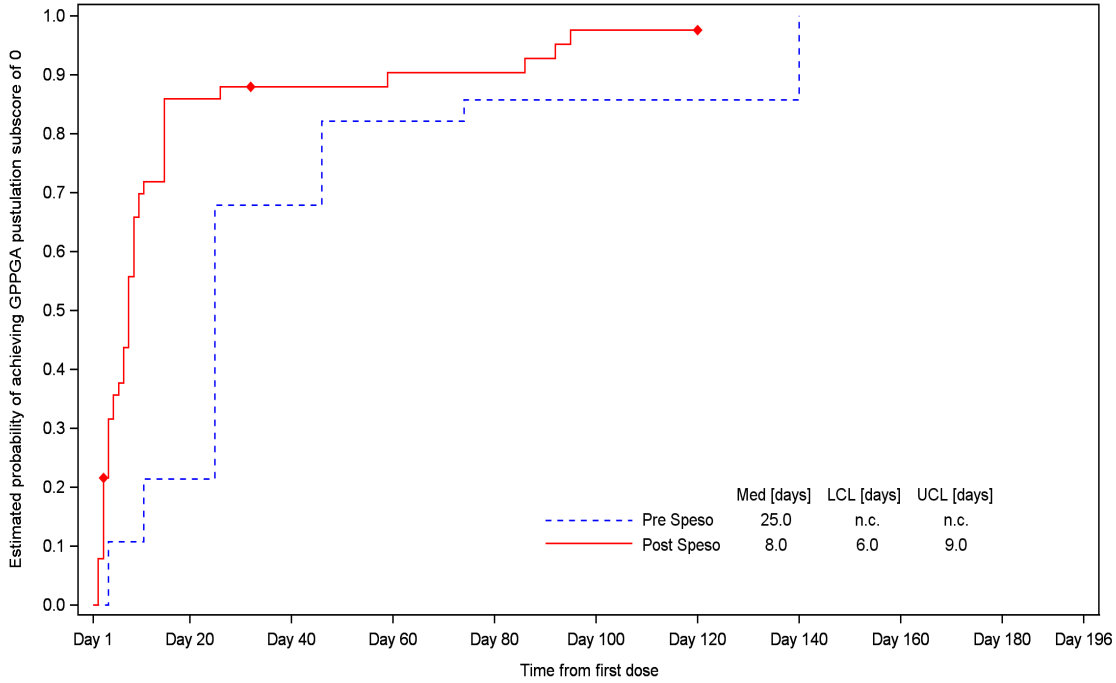
Flare type: Most severe flare
Used timepoint of the category for 'time to be completely clear from pustules' pre Speso: Mid point



Patients at risk

Pre Speso	28	22	9	5	4	4	4	4
Post Speso	51	7	5	4	4	1	1	

n.c. = not calculable.

Figure 2.5.2 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

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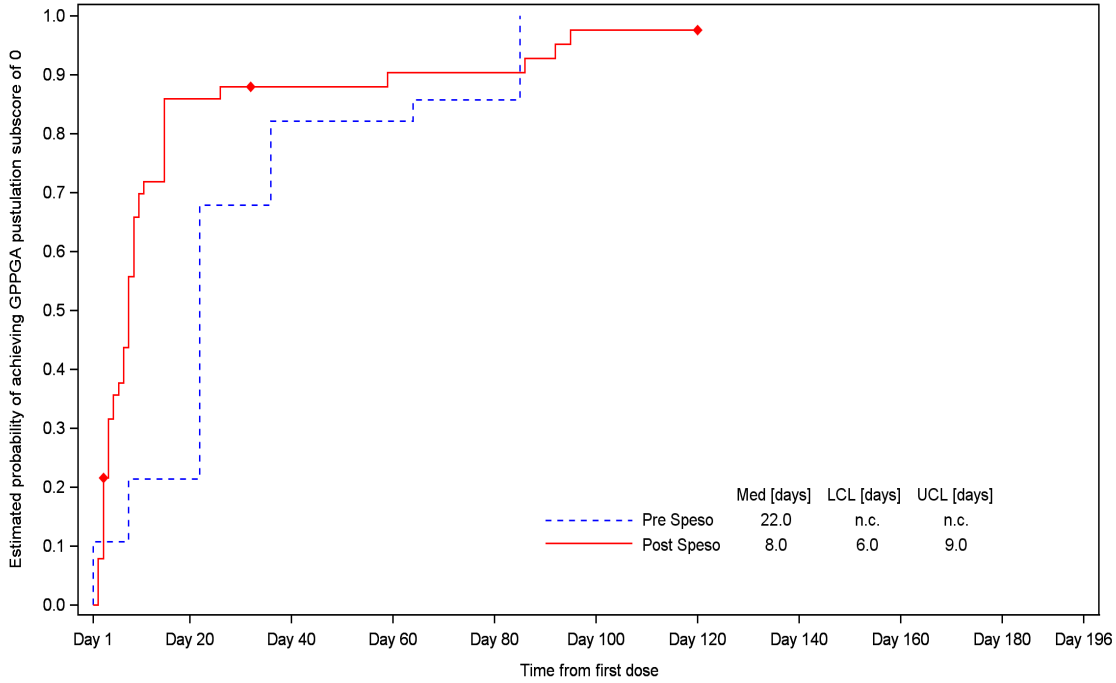
Flare type: Most severe flare
Used timepoint of the category for 'time to be completely clear from pustules' pre Speso: Left point



Patients at risk							
Pre Speso	28	22	5	5	4	0	
Post Speso	51	7	5	4	4	1	1

n.c. = not calculable.

Figure 2.5.2 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

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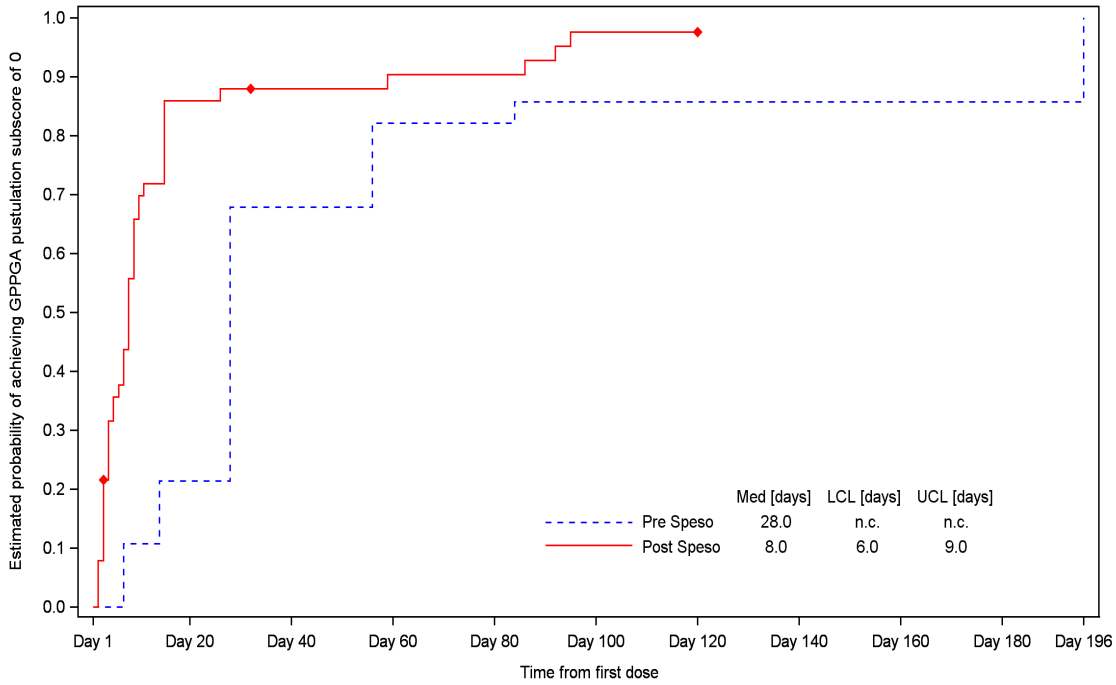
Flare type: Most severe flare
Used timepoint of the category for 'time to be completely clear from pustules' pre Speso: Right point



Patients at risk											
Pre Speso	28	22	9	5	5	4	4	4	4	4	4
Post Speso	51	7	5	4	4	1	1				

n.c. = not calculable.

Figure 2.5.2 Time to first achievement of GPPGA pustulation subscore of 0 for pre vs post Speso by flare types - RS without patients receiving Placebo only without rescue medication (OC-IR)

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1.3  Analysis for return rates
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Table 3.1 Return rates at day 1 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	18	100.0	34	97.1
EQ-5D-5L - VAS Score	18	100.0	35	100.0
FACIT-Fatigue scale	18	100.0	35	100.0
Pain VAS Score	18	100.0	34	97.1
PSS Total Score	18	100.0	35	100.0

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.2 Return rates at day 2 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	18	100.0	34	97.1
FACIT-Fatigue scale	8	44.4	16	45.7
Pain VAS Score	8	44.4	16	45.7
PSS Total Score	18	100.0	34	97.1

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.3 Return rates at day 3 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	1	2.9
EQ-5D-5L - VAS Score	18	100.0	34	97.1
FACIT-Fatigue scale	8	44.4	16	45.7
Pain VAS Score	8	44.4	16	45.7
PSS Total Score	18	100.0	34	97.1

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.4 Return rates at day 4 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	18	100.0	28	80.0
FACIT-Fatigue scale	8	44.4	12	34.3
Pain VAS Score	8	44.4	12	34.3
PSS Total Score	18	100.0	27	77.1

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.5 Return rates at day 5 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	18	100.0	26	74.3
FACIT-Fatigue scale	8	44.4	10	28.6
Pain VAS Score	8	44.4	10	28.6
PSS Total Score	18	100.0	26	74.3

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.6 Return rates at day 6 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	16	88.9	18	51.4
FACIT-Fatigue scale	7	38.9	3	8.6
Pain VAS Score	7	38.9	3	8.6
PSS Total Score	16	88.9	18	51.4

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.7 Return rates at day 7 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	17	94.4	17	48.6
FACIT-Fatigue scale	7	38.9	3	8.6
Pain VAS Score	7	38.9	3	8.6
PSS Total Score	17	94.4	17	48.6

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.8 Return rates at week 1 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	18	100.0	34	97.1
EQ-5D-5L - VAS Score	18	100.0	34	97.1
FACIT-Fatigue scale	18	100.0	34	97.1
Pain VAS Score	18	100.0	34	97.1
PSS Total Score	18	100.0	34	97.1

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.9 Return rates at week 2 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	18	100.0	33	94.3
EQ-5D-5L - VAS Score	18	100.0	33	94.3
FACIT-Fatigue scale	18	100.0	33	94.3
Pain VAS Score	18	100.0	33	94.3
PSS Total Score	18	100.0	33	94.3

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.10 Return rates at week 3 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	16	88.9	33	94.3
EQ-5D-5L - VAS Score	16	88.9	33	94.3
FACIT-Fatigue scale	15	83.3	33	94.3
Pain VAS Score	16	88.9	33	94.3
PSS Total Score	16	88.9	33	94.3

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.11 Return rates at week 4 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	15	83.3	33	94.3
EQ-5D-5L - VAS Score	15	83.3	33	94.3
FACIT-Fatigue scale	15	83.3	33	94.3
Pain VAS Score	15	83.3	33	94.3
PSS Total Score	15	83.3	33	94.3

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.12 Return rates at week 8 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	15	83.3	32	91.4
EQ-5D-5L - VAS Score	15	83.3	32	91.4
FACIT-Fatigue scale	15	83.3	32	91.4
Pain VAS Score	15	83.3	32	91.4
PSS Total Score	15	83.3	32	91.4

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.13 Return rates at week 12 by endpoint - RS

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	14	77.8	28	80.0
EQ-5D-5L - VAS Score	14	77.8	28	80.0
FACIT-Fatigue scale	14	77.8	28	80.0
Pain VAS Score	14	77.8	27	77.1
PSS Total Score	13	72.2	28	80.0

N is the number of patients in the randomized set of the respective treatment group.

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Table 3.14 Return rates at day 1 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 1)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	18	100.0	34	97.1
EQ-5D-5L - VAS Score	18	100.0	35	100.0
FACIT-Fatigue scale	18	100.0	35	100.0
Pain VAS Score	18	100.0	34	97.1
PSS Total Score	18	100.0	35	100.0

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.15 Return rates at day 2 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 2)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	18	100.0	34	97.1
FACIT-Fatigue scale	8	44.4	16	45.7
Pain VAS Score	8	44.4	16	45.7
PSS Total Score	18	100.0	34	97.1

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.16 Return rates at day 3 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 3)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	1	2.9
EQ-5D-5L - VAS Score	18	100.0	34	97.1
FACIT-Fatigue scale	8	44.4	16	45.7
Pain VAS Score	8	44.4	16	45.7
PSS Total Score	18	100.0	34	97.1

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.17 Return rates at day 4 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 4)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	18	100.0	28	80.0
FACIT-Fatigue scale	8	44.4	12	34.3
Pain VAS Score	8	44.4	12	34.3
PSS Total Score	18	100.0	27	77.1

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.18 Return rates at day 5 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 5)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	18	100.0	26	74.3
FACIT-Fatigue scale	8	44.4	10	28.6
Pain VAS Score	8	44.4	10	28.6
PSS Total Score	18	100.0	26	74.3

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.19 Return rates at day 6 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 6)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	16	88.9	18	51.4
FACIT-Fatigue scale	7	38.9	3	8.6
Pain VAS Score	7	38.9	3	8.6
PSS Total Score	16	88.9	18	51.4

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.20 Return rates at day 7 by endpoint - RS (patients without OL Speso or rescue medication intake prior to day 7)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	0	0.0	0	0.0
EQ-5D-5L - VAS Score	17	94.4	17	48.6
FACIT-Fatigue scale	7	38.9	3	8.6
Pain VAS Score	7	38.9	3	8.6
PSS Total Score	17	94.4	17	48.6

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.21 Return rates at week 1 by endpoint - RS (patients without OL Speso or rescue medication intake prior to week 1)

	Placebo (N=18)		Speso 900 mg IV SD (N=35)	
Endpoint	n	%	n	%
DLQI Total Score	18	100.0	34	97.1
EQ-5D-5L - VAS Score	18	100.0	34	97.1
FACIT-Fatigue scale	18	100.0	34	97.1
Pain VAS Score	18	100.0	34	97.1
PSS Total Score	18	100.0	34	97.1

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.22 Return rates at week 2 by endpoint - RS (patients without OL Speso or rescue medication intake prior to week 2)

	Placebo (N=3)		Speso 900 mg IV SD (N=23)	
Endpoint	n	%	n	%
DLQI Total Score	3	100.0	22	95.7
EQ-5D-5L - VAS Score	3	100.0	22	95.7
FACIT-Fatigue scale	3	100.0	22	95.7
Pain VAS Score	3	100.0	22	95.7
PSS Total Score	3	100.0	22	95.7

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.23 Return rates at week 3 by endpoint - RS (patients without OL Speso or rescue medication intake prior to week 3)

	Placebo (N=3)		Speso 900 mg IV SD (N=22)	
Endpoint	n	%	n	%
DLQI Total Score	3	100.0	21	95.5
EQ-5D-5L - VAS Score	3	100.0	21	95.5
FACIT-Fatigue scale	3	100.0	21	95.5
Pain VAS Score	3	100.0	21	95.5
PSS Total Score	3	100.0	21	95.5

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.24 Return rates at week 4 by endpoint - RS (patients without OL Speso or rescue medication intake prior to week 4)

	Placebo (N=3)		Speso 900 mg IV SD (N=22)	
Endpoint	n	%	n	%
DLQI Total Score	3	100.0	21	95.5
EQ-5D-5L - VAS Score	3	100.0	21	95.5
FACIT-Fatigue scale	3	100.0	21	95.5
Pain VAS Score	3	100.0	21	95.5
PSS Total Score	3	100.0	21	95.5

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.25 Return rates at week 8 by endpoint - RS (patients without OL Speso or rescue medication intake prior to week 8)

	Placebo (N=2)		Speso 900 mg IV SD (N=21)	
Endpoint	n	%	n	%
DLQI Total Score	2	100.0	19	90.5
EQ-5D-5L - VAS Score	2	100.0	19	90.5
FACIT-Fatigue scale	2	100.0	19	90.5
Pain VAS Score	2	100.0	19	90.5
PSS Total Score	2	100.0	19	90.5

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Table 3.26 Return rates at week 12 by endpoint - RS (patients without OL Speso or rescue medication intake prior to week 12)

	Placebo (N=2)		Speso 900 mg IV SD (N=21)	
Endpoint	n	%	n	%
DLQI Total Score	2	100.0	20	95.2
EQ-5D-5L - VAS Score	2	100.0	20	95.2
FACIT-Fatigue scale	2	100.0	20	95.2
Pain VAS Score	2	100.0	19	90.5
PSS Total Score	2	100.0	20	95.2

N is the number of patients without prior intake of OL Speso of the respective treatment group.

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Anhang 4-G2: Zusatzanalysen, EFFISAYIL ®, Intra-Placebo Vergleiche

10.4 2021 - CSAP 104: Compare Speso vs. Placebo based on patients randomized to placebo (D15 vs. D8)

Table 4.1 Odds ratio and confidence interval of Period 2 (Day 15, Spesolimab) vs. Period 1 (Day 8, Placebo) for GPPGA pustulation subscore 0 for patients randomized to placebo - RS (EN-ID8-NRI)

		Odds Ratio			
			One-sided 97.5% Confidence Interval		One-sided
	N	Estimate	Lower	Upper	p-Value
Scenario 1	18	16.817 *	2.779	Infinity	0.0002
Scenario 2	18	15.375 *	2.510	Infinity	0.0005
Scenario 3	18	11.000	1.599	Infinity	0.0032
Scenario 4	18	18.259 *	3.048	Infinity	0.0001

Scenario 1: set period 2 value for patient #1 and #2 to `response´, and patient #3 to `non-response´
Scenario 2: set period 2 value for patient #1 to `non-response´, and patient #2 to `response´, and patient #3 to `non-response´
Scenario 3: set period 2 value for all three patients to `non-response´ (the most conservative)
Scenario 4: set period 2 value for all three patients to `response´
* Median unbiased estimate (conditional MLE does not exist)

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Table 4.2 Odds ratio and confidence interval of Period 2 (Day 15, Spesolimab) vs. Period 1 (Day 8, Placebo) for GPPGA total score 0 or 1 for patients randomized to placebo - RS (EN-ID8-NRI)

		Odds Ratio			
			One-sided 97.5% Confidence Interval		One-sided
	N	Estimate	Lower	Upper	p-Value
Scenario 1	18	11.049 *	1.707	Infinity	0.0039
Scenario 2	18	8.000	1.073	Infinity	0.0195
Scenario 3	18	4.000	0.798	Infinity	0.0547
Scenario 4	18	12.491 *	1.974	Infinity	0.0020

Scenario 1: set period 2 value for patient #1 and #2 to `response´, and patient #3 to `non-response´
Scenario 2: set period 2 value for patient #1 to `non-response´, and patient #2 to `response´, and patient #3 to `non-response´
Scenario 3: set period 2 value for all three patients to `non-response´ (the most conservative)
Scenario 4: set period 2 value for all three patients to `response´
* Median unbiased estimate (conditional MLE does not exist)

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Anhang 4-G3: Zusatzanalysen, EFFISAYIL ®, Safety

1.1 Safety Analysis

1.1.1 Adverse events

Table 1.1.1 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	12	66.7	0.2	6445.6	35	27	77.1	0.3	8650.7	0.4577	10.5	(-14.9,37.8)
Sex													
Male	3	1	33.3	0.0	2435.0	14	11	78.6	0.1	8199.5	0.1936	45.2	(-16.6,85.6)
Female	15	11	73.3	0.1	7580.7	21	16	76.2	0.2	8990.8	0.9286	2.9	(-27.6,33.7)
Age													
>= 50 years	4	4	100.0	0.0	18262.5	11	7	63.6	0.1	7102.1	0.2581	-36.4	(-69.2,26.6)
< 50 years	14	8	57.1	0.2	4870.0	24	20	83.3	0.2	9365.4	0.0997	26.2	(-4.2,56.2)
Race													
Asian	13	9	69.2	0.1	6848.4	16	13	81.3	0.1	8959.0	0.6129	12.0	(-21.0,45.6)
White	5	3	60.0	0.1	5478.8	19	14	73.7	0.2	8382.8	0.7314	13.7	(-28.7,60.8)
Region													
Europe + Africa + US	5	3	60.0	0.1	5478.8	21	16	76.2	0.2	9131.3	0.5806	16.2	(-24.9,63.0)
Asia(ex Japan) + Japan	13	9	69.2	0.1	6848.4	14	11	78.6	0.1	8035.5	0.7168	9.3	(-25.4,43.3)
BMI													
< 25 kg/m2	9	7	77.8	0.1	8522.5	15	9	60.0	0.2	5767.1	0.4783	-17.8	(-52.3,25.7)
25 to < 30 kg/m2	6	3	50.0	0.1	4058.3	10	9	90.0	0.1	10957.5	0.1402	40.0	(-10.6,80.0)
>= 30 kg/m2	3	2	66.7	0.0	6640.9	10	9	90.0	0.1	12175.0	0.4759	23.3	(-26.4,80.5)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.1 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.69	(0.45,6.06)	1.16	(0.82,1.96) (0.80,1.68)	
Sex					0.3361
Male	7.33	(0.38,233.53)	2.36	(0.78,70.99) (0.46,11.95)	
Female	1.16	(0.23,5.62)	1.04	(0.69,1.84) (0.71,1.53)	
Age					0.0140
>= 50 years	0.00	(0.00,1.98)	0.64	(0.31,1.76) (0.41,0.99)	
< 50 years	3.75	(0.78,18.24)	1.46	(0.94,3.07) (0.90,2.37)	
Race					0.9194
Asian	1.93	(0.31,12.36)	1.17	(0.73,2.28) (0.76,1.81)	
White	1.87	(0.17,15.96)	1.23	(0.67,8.69) (0.57,2.64)	
Region					0.8026
Europe + Africa + US	2.13	(0.20,18.02)	1.27	(0.71,7.87) (0.60,2.70)	
Asia(ex Japan) + Japan	1.63	(0.26,10.65)	1.13	(0.69,2.12) (0.72,1.79)	
BMI					0.1988
< 25 kg/m2	0.43	(0.05,2.88)	0.77	(0.41,1.76) (0.45,1.33)	
25 to < 30 kg/m2	9.00	(0.60,260.11)	1.80	(0.86,8.56) (0.79,4.11)	
>= 30 kg/m2	4.50	(0.08,193.03)	1.35	(0.70,9.77) (0.59,3.08)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.1 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	2	100.0			5	4	80.0					
No	12	7	58.3			24	18	75.0					
Mutation status IL36RN after DNA resequencing													
Yes	6	6	100.0	0.0	19922.7	8	6	75.0	0.1	10957.5	0.2711	-25.0	(-66.1,23.6)
No	11	5	45.5	0.2	3261.2	21	16	76.2	0.2	8005.5	0.1280	30.7	(-5.7,62.9)
Baseline GPPGA pustulation subscore													
<4	12	9	75.0	0.1	7471.0	22	16	72.7	0.2	8231.0	0.9629	-2.3	(-31.9,33.0)
=4	6	3	50.0	0.1	4565.6	13	11	84.6	0.1	9343.6	0.1509	34.6	(-11.2,75.4)
Baseline GPPGA score													
=3	15	10	66.7	0.2	6190.7	28	21	75.0	0.2	8522.5	0.7551	8.3	(-19.7,39.3)
=4	3	2	66.7	0.0	8116.7	7	6	85.7	0.1	9131.3	0.8467	19.0	(-39.0,79.3)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	5	83.3					
No	15	12	80.0			29	22	75.9					
Background treatment prior to randomization													
Yes	8	5	62.5	0.1	5707.0	15	10	66.7	0.1	7305.0	0.9080	4.2	(-35.9,46.6)
No	10	7	70.0	0.1	7102.1	20	17	85.0	0.2	9702.0	0.4605	15.0	(-16.5,51.1)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.1 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.0482
Yes	0.00	(0.00,2.80)	0.75	(0.35,1.40) (0.50,1.12)	
No	3.84	(0.76,19.18)	1.68	(0.92,7.53) (0.84,3.34)	
Baseline GPPGA pustulation subscore					0.2409
<4	0.89	(0.15,4.55)	0.97	(0.63,1.73) (0.64,1.47)	
=4	5.50	(0.52,59.14)	1.69	(0.85,6.67) (0.74,3.89)	
Baseline GPPGA score					0.7833
=3	1.50	(0.35,6.08)	1.13	(0.75,2.05) (0.74,1.71)	
=4	3.00	(0.05,135.02)	1.29	(0.56,9.41) (0.55,3.02)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7459
Yes	1.20	(0.17,7.63)	1.07	(0.56,2.85) (0.56,2.03)	
No	2.43	(0.33,16.89)	1.21	(0.79,2.65) (0.78,1.90)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.1 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	10	62.5			34	27	79.4				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	12	66.7			32	24	75.0				
Renal impairment at baseline												
Normal	16	10	62.5			26	20	76.9				
Mild	1	1	100.0			6	5	83.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.1 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.2 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	13	72.2	0.2	5217.9	35	28	80.0	0.6	5013.2	0.7740	7.8	(-15.9,34.8)
Sex													
Male	3	2	66.7	0.0	4565.6	14	11	78.6	0.3	4320.2	1.0000	11.9	(-35.2,70.8)
Female	15	11	73.3	0.2	5357.0	21	17	81.0	0.3	5593.9	0.6757	7.6	(-22.4,38.1)
Age													
>= 50 years	4	4	100.0	0.0	18262.5	11	7	63.6	0.2	3195.9	0.2581	-36.4	(-69.2,26.6)
< 50 years	14	9	64.3	0.2	3960.5	24	21	87.5	0.3	6185.7	0.1149	23.2	(-5.5,53.1)
Race													
Asian	13	10	76.9	0.2	5144.4	16	13	81.3	0.3	3990.1	0.8549	4.3	(-27.4,37.4)
White	5	3	60.0	0.1	5478.8	19	15	78.9	0.2	6445.6	0.5229	18.9	(-23.9,65.3)
Region													
Europe + Africa + US	5	3	60.0	0.1	5478.8	21	17	81.0	0.2	7056.0	0.4180	21.0	(-20.9,67.1)
Asia(ex Japan) + Japan	13	10	76.9	0.2	5144.4	14	11	78.6	0.3	3463.6	1.0000	1.6	(-31.7,36.3)
BMI													
< 25 kg/m2	9	7	77.8	0.1	8522.5	15	10	66.7	0.3	2922.0	0.7038	-11.1	(-46.1,30.8)
25 to < 30 kg/m2	6	4	66.7	0.1	2922.0	10	9	90.0	0.1	6321.6	0.4301	23.3	(-23.1,68.2)
>= 30 kg/m2	3	2	66.7	0.0	6640.9	10	9	90.0	0.1	12175.0	0.4759	23.3	(-26.4,80.5)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.2 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.54	(0.38,5.91)	1.11	(0.81,1.73) (0.80,1.54)	
Sex					0.8894
Male	1.83	(0.05,31.08)	1.18	(0.62,11.61) (0.51,2.75)	
Female	1.55	(0.29,8.14)	1.10	(0.75,1.90) (0.76,1.60)	
Age					0.0149
>= 50 years	0.00	(0.00,1.98)	0.64	(0.31,1.76) (0.41,0.99)	
< 50 years	3.89	(0.71,22.71)	1.36	(0.92,2.44) (0.90,2.07)	
Race					0.6093
Asian	1.30	(0.19,8.99)	1.06	(0.69,1.82) (0.72,1.54)	
White	2.50	(0.22,22.15)	1.32	(0.73,8.69) (0.62,2.79)	
Region					0.5199
Europe + Africa + US	2.83	(0.25,24.84)	1.35	(0.77,7.87) (0.64,2.84)	
Asia(ex Japan) + Japan	1.10	(0.16,7.75)	1.02	(0.63,1.70) (0.68,1.53)	
BMI					0.4431
< 25 kg/m2	0.57	(0.06,3.96)	0.86	(0.47,1.76) (0.52,1.41)	
25 to < 30 kg/m2	4.50	(0.25,146.11)	1.35	(0.76,4.78) (0.74,2.47)	
>= 30 kg/m2	4.50	(0.08,193.03)	1.35	(0.70,9.77) (0.59,3.08)	

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.2 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	2	100.0			5	5	100.0					
No	12	7	58.3			24	18	75.0					
Mutation status IL36RN after DNA resequencing													
Yes	6	6	100.0	0.0	19922.7	8	7	87.5	0.1	5810.8	0.6093	-12.5	(-52.7,33.7)
No	11	6	54.5	0.2	2774.1	21	16	76.2	0.3	4994.9	0.3159	21.6	(-13.4,55.7)
Baseline GPPGA pustulation subscore													
<4	12	9	75.0	0.1	7471.0	22	17	77.3	0.4	3856.7	0.9276	2.3	(-27.1,36.0)
=4	6	4	66.7	0.1	3108.5	13	11	84.6	0.1	9343.6	0.4859	17.9	(-23.8,64.2)
Baseline GPPGA score													
=3	15	11	73.3	0.2	4899.7	28	22	78.6	0.5	4464.2	0.8304	5.2	(-21.0,35.0)
=4	3	2	66.7	0.0	8116.7	7	6	85.7	0.1	9131.3	0.8467	19.0	(-39.0,79.3)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	5	83.3					
No	15	12	80.0			29	23	79.3					
Background treatment prior to randomization													
Yes	8	5	62.5	0.1	5707.0	15	10	66.7	0.3	3885.6	0.9080	4.2	(-35.9,46.6)
No	10	8	80.0	0.2	4952.5	20	18	90.0	0.3	5976.8	0.5224	10.0	(-17.8,45.7)

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.2 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.1556
Yes	0.00	(0.00,12.00)	0.88	(0.47,1.73) (0.67,1.14)	
No	2.67	(0.52,13.28)	1.40	(0.82,3.79) (0.77,2.52)	
Baseline GPPGA pustulation subscore					0.5752
<4	1.13	(0.18,6.09)	1.03	(0.69,1.78) (0.69,1.53)	
=4	2.75	(0.21,32.52)	1.27	(0.71,6.54) (0.69,2.34)	
Baseline GPPGA score					0.7004
=3	1.33	(0.28,5.90)	1.07	(0.74,1.76) (0.75,1.54)	
=4	3.00	(0.05,135.02)	1.29	(0.56,9.41) (0.55,3.02)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8864
Yes	1.20	(0.17,7.63)	1.07	(0.56,2.85) (0.56,2.03)	
No	2.25	(0.20,24.21)	1.13	(0.81,1.94) (0.80,1.58)	

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Table 1.1.2 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	11	68.8			34	28	82.4				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	13	72.2			32	25	78.1				
Renal impairment at baseline												
Normal	16	11	68.8			26	21	80.8				
Mild	1	1	100.0			6	5	83.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.1.2 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.1.3 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	13	72.2	0.4	3230.1	35	29	82.9	1.1	2596.1	0.4577	10.6	(-12.6,37.4)
Sex													
Male	3	2	66.7	0.0	4565.6	14	12	85.7	0.5	2356.5	0.6084	19.0	(-27.4,76.5)
Female	15	11	73.3	0.4	3067.0	21	17	81.0	0.6	2797.0	0.6757	7.6	(-22.4,38.1)
Age													
>= 50 years	4	4	100.0	0.0	18262.5	11	7	63.6	0.5	1331.6	0.2581	-36.4	(-69.2,26.6)
< 50 years	14	9	64.3	0.4	2364.9	24	22	91.7	0.6	3720.1	0.0631	27.4	(-1.3,56.6)
Race													
Asian	13	10	76.9	0.3	2876.0	16	13	81.3	0.8	1660.2	0.8549	4.3	(-27.4,37.4)
White	5	3	60.0	0.1	5478.8	19	16	84.2	0.3	4790.2	0.2980	24.2	(-17.7,71.6)
Region													
Europe + Africa + US	5	3	60.0	0.1	5478.8	21	18	85.7	0.3	5259.6	0.2656	25.7	(-15.1,71.6)
Asia(ex Japan) + Japan	13	10	76.9	0.3	2876.0	14	11	78.6	0.8	1419.7	1.0000	1.6	(-31.7,36.3)
BMI													
< 25 kg/m2	9	7	77.8	0.1	8522.5	15	11	73.3	0.8	1466.3	0.8951	-4.4	(-39.3,36.6)
25 to < 30 kg/m2	6	4	66.7	0.3	1378.3	10	9	90.0	0.3	3072.2	0.4301	23.3	(-23.1,68.2)
>= 30 kg/m2	3	2	66.7	0.0	6640.9	10	9	90.0	0.1	12175.0	0.4759	23.3	(-26.4,80.5)

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Table 1.1.3 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.86	(0.44,7.46)	1.15	(0.85,1.79) (0.83,1.59)	
Sex					0.7417
Male	3.00	(0.07,55.70)	1.29	(0.71,11.61) (0.56,2.94)	
Female	1.55	(0.29,8.14)	1.10	(0.75,1.90) (0.76,1.60)	
Age					0.0090
>= 50 years	0.00	(0.00,1.98)	0.64	(0.31,1.76) (0.41,0.99)	
< 50 years	6.11	(0.96,49.90)	1.43	(0.98,2.62) (0.95,2.15)	
Race					0.5037
Asian	1.30	(0.19,8.99)	1.06	(0.69,1.82) (0.72,1.54)	
White	3.56	(0.29,33.96)	1.40	(0.81,8.69) (0.67,2.95)	
Region					0.4340
Europe + Africa + US	4.00	(0.33,37.85)	1.43	(0.83,7.87) (0.68,2.98)	
Asia(ex Japan) + Japan	1.10	(0.16,7.75)	1.02	(0.63,1.70) (0.68,1.53)	
BMI					0.5784
< 25 kg/m2	0.79	(0.08,5.78)	0.94	(0.56,1.80) (0.59,1.50)	
25 to < 30 kg/m2	4.50	(0.25,146.11)	1.35	(0.76,4.78) (0.74,2.47)	
>= 30 kg/m2	4.50	(0.08,193.03)	1.35	(0.70,9.77) (0.59,3.08)	

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Table 1.1.3 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	2	100.0			5	5	100.0					
No	12	7	58.3			24	18	75.0					
Mutation status IL36RN after DNA resequencing													
Yes	6	6	100.0	0.0	19922.7	8	7	87.5	0.3	2556.8	0.6093	-12.5	(-52.7,33.7)
No	11	6	54.5	0.4	1623.3	21	16	76.2	0.6	2563.2	0.3159	21.6	(-13.4,55.7)
Baseline GPPGA pustulation subscore													
<4	12	9	75.0	0.1	7471.0	22	18	81.8	1.0	1801.2	0.7463	6.8	(-22.1,40.3)
=4	6	4	66.7	0.3	1418.4	13	11	84.6	0.1	9343.6	0.4859	17.9	(-23.8,64.2)
Baseline GPPGA score													
=3	15	11	73.3	0.4	2911.4	28	23	82.1	1.1	2187.7	0.7550	8.8	(-17.0,38.4)
=4	3	2	66.7	0.0	8116.7	7	6	85.7	0.1	9131.3	0.8467	19.0	(-39.0,79.3)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	5	83.3					
No	15	12	80.0			29	24	82.8					
Background treatment prior to randomization													
Yes	8	5	62.5	0.1	5707.0	15	10	66.7	0.6	1773.1	0.9080	4.2	(-35.9,46.6)
No	10	8	80.0	0.3	2540.9	20	19	95.0	0.6	3435.5	0.3644	15.0	(-12.0,49.7)

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Table 1.1.3 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.1556
Yes	0.00	(0.00,12.00)	0.88	(0.47,1.73) (0.67,1.14)	
No	2.67	(0.52,13.28)	1.40	(0.82,3.79) (0.77,2.52)	
Baseline GPPGA pustulation subscore					0.6805
<4	1.50	(0.23,8.74)	1.09	(0.74,1.94) (0.74,1.60)	
=4	2.75	(0.21,32.52)	1.27	(0.71,6.54) (0.69,2.34)	
Baseline GPPGA score					0.7701
=3	1.67	(0.33,7.84)	1.12	(0.79,1.82) (0.79,1.59)	
=4	3.00	(0.05,135.02)	1.29	(0.56,9.41) (0.55,3.02)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7710
Yes	1.20	(0.17,7.63)	1.07	(0.56,2.85) (0.56,2.03)	
No	4.75	(0.30,146.73)	1.19	(0.88,2.12) (0.86,1.64)	

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Table 1.1.3 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	11	68.8			34	29	85.3				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	13	72.2			32	26	81.3				
Renal impairment at baseline												
Normal	16	11	68.8			26	22	84.6				
Mild	1	1	100.0			6	5	83.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Table 1.1.3 Proportion and incidence rate of patients with any adverse events overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.4 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	987.2	35	5	14.3	0.6	833.9	0.8862	-2.4	(-28.5,17.7)
Sex													
Male	3	0	0.0			14	3	21.4					
Female	15	3	20.0			21	2	9.5					
Age													
>= 50 years	4	1	25.0			11	2	18.2					
< 50 years	14	2	14.3			24	3	12.5					
Race													
Asian	13	3	23.1			16	2	12.5					
White	5	0	0.0			19	3	15.8					
Region													
Europe + Africa + US	5	0	0.0			21	4	19.0					
Asia(ex Japan) + Japan	13	3	23.1			14	1	7.1					
BMI													
< 25 kg/m2	9	3	33.3			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	2	20.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.4 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.4 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	2	40.0				
No	12	3	25.0			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	2	25.0				
No	11	2	18.2			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	2	16.7			22	2	9.1				
=4	6	1	16.7			13	3	23.1				
Baseline GPPGA score												
=3	15	3	20.0			28	4	14.3				
=4	3	0	0.0			7	1	14.3				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	2	33.3				
No	15	3	20.0			29	3	10.3				
Background treatment prior to randomization												
Yes	8	2	25.0			15	2	13.3				
No	10	1	10.0			20	3	15.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.4 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.4 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	3	18.8			34	5	14.7				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	3	16.7			32	4	12.5				
Renal impairment at baseline												
Normal	16	2	12.5			26	4	15.4				
Mild	1	1	100.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.4 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.5 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	702.4	35	5	14.3	1.6	304.9	0.8862	-2.4	(-28.5,17.7)
Sex													
Male	3	0	0.0			14	3	21.4					
Female	15	3	20.0			21	2	9.5					
Age													
>= 50 years	4	1	25.0			11	2	18.2					
< 50 years	14	2	14.3			24	3	12.5					
Race													
Asian	13	3	23.1			16	2	12.5					
White	5	0	0.0			19	3	15.8					
Region													
Europe + Africa + US	5	0	0.0			21	4	19.0					
Asia(ex Japan) + Japan	13	3	23.1			14	1	7.1					
BMI													
< 25 kg/m2	9	3	33.3			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	2	20.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.5 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.5 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	2	40.0				
No	12	3	25.0			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	2	25.0				
No	11	2	18.2			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	2	16.7			22	2	9.1				
=4	6	1	16.7			13	3	23.1				
Baseline GPPGA score												
=3	15	3	20.0			28	4	14.3				
=4	3	0	0.0			7	1	14.3				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	2	33.3				
No	15	3	20.0			29	3	10.3				
Background treatment prior to randomization												
Yes	8	2	25.0			15	2	13.3				
No	10	1	10.0			20	3	15.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.5 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.5 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	3	18.8			34	5	14.7				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	3	16.7			32	4	12.5				
Renal impairment at baseline												
Normal	16	2	12.5			26	4	15.4				
Mild	1	1	100.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.5 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.6 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.7	408.9	35	6	17.1	4.1	146.3	1.0000	0.5	(-25.6,21.2)
Sex													
Male	3	0	0.0			14	3	21.4					
Female	15	3	20.0			21	3	14.3					
Age													
>= 50 years	4	1	25.0			11	2	18.2					
< 50 years	14	2	14.3			24	4	16.7					
Race													
Asian	13	3	23.1			16	2	12.5					
White	5	0	0.0			19	4	21.1					
Region													
Europe + Africa + US	5	0	0.0			21	5	23.8					
Asia(ex Japan) + Japan	13	3	23.1			14	1	7.1					
BMI													
< 25 kg/m2	9	3	33.3			15	2	13.3					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	2	20.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.6 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.6 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	2	40.0				
No	12	3	25.0			24	4	16.7				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	2	25.0				
No	11	2	18.2			21	4	19.0				
Baseline GPPGA pustulation subscore												
<4	12	2	16.7			22	2	9.1				
=4	6	1	16.7			13	4	30.8				
Baseline GPPGA score												
=3	15	3	20.0			28	5	17.9				
=4	3	0	0.0			7	1	14.3				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	2	33.3				
No	15	3	20.0			29	4	13.8				
Background treatment prior to randomization												
Yes	8	2	25.0			15	2	13.3				
No	10	1	10.0			20	4	20.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.6 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.6 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	3	18.8			34	6	17.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	3	16.7			32	5	15.6				
Renal impairment at baseline												
Normal	16	2	12.5			26	5	19.2				
Mild	1	1	100.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.6 Proportion and incidence rate of patients with serious adverse events overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.3	1790.4	35	13	37.1	0.5	2512.3	0.7740	9.4	(-19.5,34.4)
Sex													
Male	3	0	0.0	0.1	0.0	14	5	35.7	0.2	2174.1	0.3501	35.7	(-35.2,66.5)
Female	15	5	33.3	0.2	2254.6	21	8	38.1	0.3	2782.9	0.8933	4.8	(-28.4,35.8)
Age													
>= 50 years	4	3	75.0	0.0	7826.8	11	3	27.3	0.2	1857.2	0.2581	-47.7	(-84.6,15.1)
< 50 years	14	2	14.3	0.2	830.1	24	10	41.7	0.4	2809.6	0.0997	27.4	(-6.8,52.9)
Race													
Asian	13	4	30.8	0.2	2001.4	16	8	50.0	0.2	3794.8	0.4475	19.2	(-18.0,52.8)
White	5	1	20.0	0.1	1259.5	19	5	26.3	0.3	1630.6	1.0000	6.3	(-46.1,40.8)
Region													
Europe + Africa + US	5	1	20.0	0.1	1259.5	21	6	28.6	0.3	1811.2	1.0000	8.6	(-41.9,41.9)
Asia(ex Japan) + Japan	13	4	30.8	0.2	2001.4	14	7	50.0	0.2	3759.9	0.4965	19.2	(-19.4,55.4)
BMI													
< 25 kg/m2	9	1	11.1			15	3	20.0					
25 to < 30 kg/m2	6	3	50.0			10	5	50.0					
>= 30 kg/m2	3	1	33.3			10	5	50.0					

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.54	(0.44,5.74)	1.34	(0.58,6.14) (0.57,3.16)	
Sex					NC
Male	inf	(0.37, inf)	inf	(0.40, inf)	
Female	1.23	(0.30,5.29)	1.14	(0.46,3.47) (0.46,2.81)	
Age					0.0209
>= 50 years	0.13	(0.00,1.90)	0.36	(0.09,1.43) (0.12,1.11)	
< 50 years	4.29	(0.81,32.49)	2.92	(0.86,31.61) (0.74,11.45)	
Race					0.8461
Asian	2.25	(0.47,11.33)	1.63	(0.63,7.11) (0.63,4.21)	
White	1.43	(0.13,42.05)	1.32	(0.24,33.81) (0.20,8.87)	
Region					0.9049
Europe + Africa + US	1.60	(0.16,45.83)	1.43	(0.30,37.00) (0.22,9.35)	
Asia(ex Japan) + Japan	2.25	(0.44,11.81)	1.63	(0.62,5.95) (0.62,4.28)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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Table 1.1.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	1	20.0					
No	12	2	16.7			24	9	37.5					
Mutation status IL36RN after DNA resequencing													
Yes	6	4	66.7			8	3	37.5					
No	11	1	9.1			21	7	33.3					
Baseline GPPGA pustulation subscore													
<4	12	4	33.3	0.2	2213.6	22	7	31.8	0.3	2166.7	1.0000	-1.5	(-37.1,30.3)
=4	6	1	16.7	0.1	1014.6	13	6	46.2	0.2	3086.6	0.3309	29.5	(-20.6,64.9)
Baseline GPPGA score													
=3	15	4	26.7	0.2	1679.3	28	9	32.1	0.4	2134.6	0.8403	5.5	(-25.8,32.4)
=4	3	1	33.3	0.0	2435.0	7	4	57.1	0.1	4174.3	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	3	50.0					
No	15	5	33.3			29	10	34.5					
Background treatment prior to randomization													
Yes	8	1	12.5	0.1	689.2	15	4	26.7	0.2	1781.7	0.5266	14.2	(-26.5,46.4)
No	10	4	40.0	0.1	2981.6	20	9	45.0	0.3	3072.2	0.9026	5.0	(-33.8,40.9)

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MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.3283
<4	0.93	(0.20,4.65)	0.95	(0.35,3.82) (0.35,2.61)	
=4	4.29	(0.40,117.75)	2.77	(0.59,73.58) (0.42,18.20)	
Baseline GPPGA score					0.7289
=3	1.30	(0.32,5.86)	1.21	(0.46,7.59) (0.44,3.27)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.5701
Yes	2.55	(0.25,71.42)	2.13	(0.32,54.74) (0.28,16.02)	
No	1.23	(0.25,6.32)	1.13	(0.45,5.99) (0.46,2.77)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	3	18.8			34	13	38.2				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	5	27.8			32	12	37.5				
Renal impairment at baseline												
Normal	16	4	25.0			26	10	38.5				
Mild	1	0	0.0			6	2	33.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.5	1043.6	35	9	25.7	1.7	538.9	0.9152	-2.1	(-30.0,22.2)
Sex													
Male	3	1	33.3			14	4	28.6					
Female	15	4	26.7			21	5	23.8					
Age													
>= 50 years	4	2	50.0			11	3	27.3					
< 50 years	14	3	21.4			24	6	25.0					
Race													
Asian	13	4	30.8	0.4	1000.7	16	6	37.5	0.8	777.1	0.8076	6.7	(-30.0,42.4)
White	5	1	20.0	0.1	1259.5	19	3	15.8	0.9	334.1	1.0000	-4.2	(-54.5,29.8)
Region													
Europe + Africa + US	5	1	20.0			21	4	19.0					
Asia(ex Japan) + Japan	13	4	30.8			14	5	35.7					
BMI													
< 25 kg/m2	9	1	11.1			15	2	13.3					
25 to < 30 kg/m2	6	3	50.0			10	5	50.0					
>= 30 kg/m2	3	1	33.3			10	2	20.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.90	(0.25,3.52)	0.93	(0.36,2.95) (0.36,2.36)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					0.7094
Asian	1.35	(0.27,7.01)	1.22	(0.41,4.47) (0.43,3.42)	
White	0.75	(0.06,24.46)	0.79	(0.10,20.36) (0.10,6.06)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	0	0.0					
No	12	2	16.7			24	7	29.2					
Mutation status IL36RN after DNA resequencing													
Yes	6	3	50.0			8	2	25.0					
No	11	2	18.2			21	5	23.8					
Baseline GPPGA pustulation subscore													
<4	12	3	25.0			22	4	18.2					
=4	6	2	33.3			13	5	38.5					
Baseline GPPGA score													
=3	15	4	26.7	0.4	913.1	28	6	21.4	1.5	397.0	0.8304	-5.2	(-35.0,21.0)
=4	3	1	33.3	0.0	2435.0	7	3	42.9	0.2	1889.2	0.9428	9.5	(-58.8,65.2)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	2	33.3					
No	15	4	26.7			29	7	24.1					
Background treatment prior to randomization													
Yes	8	1	12.5	0.2	487.0	15	2	13.3	0.7	294.6	1.0000	0.8	(-39.5,32.0)
No	10	4	40.0	0.3	1461.0	20	7	35.0	1.0	706.3	0.8978	-5.0	(-43.3,30.8)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					0.6641
=3	0.75	(0.17,3.61)	0.80	(0.26,3.04) (0.27,2.41)	
=4	1.50	(0.07,58.21)	1.29	(0.23,33.89) (0.21,7.89)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8736
Yes	1.08	(0.07,36.08)	1.07	(0.10,28.84) (0.11,10.04)	
No	0.81	(0.16,4.28)	0.88	(0.32,3.33) (0.33,2.30)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	3	18.8			34	9	26.5				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	5	27.8			32	8	25.0				
Renal impairment at baseline												
Normal	16	4	25.0			26	6	23.1				
Mild	1	0	0.0			6	2	33.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.8	606.7	35	8	22.9	4.7	171.3	0.7741	-4.9	(-32.3,19.1)
Sex													
Male	3	1	33.3			14	3	21.4					
Female	15	4	26.7			21	5	23.8					
Age													
>= 50 years	4	2	50.0			11	3	27.3					
< 50 years	14	3	21.4			24	5	20.8					
Race													
Asian	13	4	30.8			16	5	31.3					
White	5	1	20.0			19	3	15.8					
Region													
Europe + Africa + US	5	1	20.0			21	4	19.0					
Asia(ex Japan) + Japan	13	4	30.8			14	4	28.6					
BMI													
< 25 kg/m2	9	1	11.1			15	3	20.0					
25 to < 30 kg/m2	6	3	50.0			10	3	30.0					
>= 30 kg/m2	3	1	33.3			10	2	20.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.77	(0.21,3.07)	0.82	(0.31,2.76) (0.31,2.15)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	0	0.0					
No	12	2	16.7			24	5	20.8					
Mutation status IL36RN after DNA resequencing													
Yes	6	3	50.0			8	2	25.0					
No	11	2	18.2			21	3	14.3					
Baseline GPPGA pustulation subscore													
<4	12	3	25.0			22	4	18.2					
=4	6	2	33.3			13	4	30.8					
Baseline GPPGA score													
=3	15	4	26.7	0.8	510.8	28	6	21.4	4.1	144.8	0.8304	-5.2	(-35.0,21.0)
=4	3	1	33.3	0.0	2435.0	7	2	28.6	0.5	378.5	1.0000	-4.8	(-70.8,53.0)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	1	16.7					
No	15	4	26.7			29	7	24.1					
Background treatment prior to randomization													
Yes	8	1	12.5	0.2	410.4	15	2	13.3	1.7	114.7	1.0000	0.8	(-39.5,32.0)
No	10	4	40.0	0.6	689.2	20	6	30.0	2.9	205.0	0.7850	-10.0	(-47.7,25.7)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					0.9555
=3	0.75	(0.17,3.61)	0.80	(0.26,3.04) (0.27,2.41)	
=4	0.80	(0.04,34.87)	0.86	(0.10,23.16) (0.12,6.23)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7790
Yes	1.08	(0.07,36.08)	1.07	(0.10,28.84) (0.11,10.04)	
No	0.64	(0.13,3.50)	0.75	(0.26,2.75) (0.27,2.06)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	3	18.8			34	8	23.5				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	5	27.8			32	7	21.9				
Renal impairment at baseline												
Normal	16	4	25.0			26	5	19.2				
Mild	1	0	0.0			6	2	33.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.3	1706.8	35	8	22.9	0.6	1404.8	0.7741	-4.9	(-32.3,19.1)
Sex													
Male	3	1	33.3			14	3	21.4					
Female	15	4	26.7			21	5	23.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	5	35.7	0.2	2311.7	24	8	33.3	0.4	2164.4	0.9344	-2.4	(-35.2,28.2)
Race													
Asian	13	3	23.1			16	5	31.3					
White	5	2	40.0			19	3	15.8					
Region													
Europe + Africa + US	5	2	40.0			21	4	19.0					
Asia(ex Japan) + Japan	13	3	23.1			14	4	28.6					
BMI													
< 25 kg/m2	9	4	44.4			15	5	33.3					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	1	33.3			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.77	(0.21,3.07)	0.82	(0.31,2.76) (0.31,2.15)	
Sex					
Male					
Female					
Age					NC
>= 50 years					
< 50 years	0.90	(0.22,3.88)	0.93	(0.37,2.87) (0.38,2.30)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)	
Mutation status IL36RN													
Yes	2	1	50.0			5	1	20.0					
No	12	3	25.0			24	6	25.0					
Mutation status IL36RN after DNA resequencing													
Yes	6	2	33.3			8	1	12.5					
No	11	2	18.2			21	6	28.6					
Baseline GPPGA pustulation subscore													
<4	12	4	33.3			22	5	22.7					
=4	6	1	16.7			13	3	23.1					
Baseline GPPGA score													
=3	15	4	26.7	0.3	1588.0	28	7	25.0	0.4	1559.0	0.9616	-1.7	(-32.2,24.9)
=4	3	1	33.3	0.0	2435.0	7	1	14.3	0.1	830.1	0.8467	-19.0	(-79.3,39.0)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	0	0.0					
No	15	5	33.3			29	8	27.6					
Background treatment prior to randomization													
Yes	8	2	25.0			15	3	20.0					
No	10	3	30.0			20	5	25.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					0.5612
=3	0.92	(0.22,4.29)	0.94	(0.32,4.04) (0.33,2.70)	
=4	0.33	(0.01,19.29)	0.43	(0.01,13.81) (0.04,4.82)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	5	31.3			34	8	23.5				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	5	27.8			32	7	21.9				
Renal impairment at baseline												
Normal	16	5	31.3			26	7	26.9				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	6	33.3	0.4	1432.4	35	13	37.1	1.3	971.0	0.8862	3.8	(-25.4,30.0)
Sex													
Male	3	1	33.3	0.0	2282.8	14	4	28.6	0.6	664.1	1.0000	-4.8	(-64.8,42.6)
Female	15	5	33.3	0.4	1333.0	21	9	42.9	0.7	1222.0	0.6757	9.5	(-24.0,40.5)
Age													
>= 50 years	4	1	25.0	0.1	1259.5	11	0	0.0	0.6	0.0	0.2576	-25.0	(-80.6,14.6)
< 50 years	14	5	35.7	0.3	1472.8	24	13	54.2	0.8	1671.9	0.4302	18.5	(-17.4,48.7)
Race													
Asian	13	4	30.8	0.3	1150.4	16	7	43.8	0.7	1047.8	0.6179	13.0	(-24.1,47.5)
White	5	2	40.0	0.1	2809.6	19	6	31.6	0.7	894.5	1.0000	-8.4	(-56.5,34.1)
Region													
Europe + Africa + US	5	2	40.0	0.1	2809.6	21	7	33.3	0.7	987.2	1.0000	-6.7	(-54.5,34.9)
Asia(ex Japan) + Japan	13	4	30.8	0.3	1150.4	14	6	42.9	0.6	952.8	0.6332	12.1	(-25.6,47.9)
BMI													
< 25 kg/m2	9	4	44.4	0.2	2087.1	15	7	46.7	0.6	1172.8	1.0000	2.2	(-39.6,42.3)
25 to < 30 kg/m2	6	1	16.7	0.2	553.4	10	2	20.0	0.4	566.3	1.0000	3.3	(-46.2,44.9)
>= 30 kg/m2	3	1	33.3	0.0	2148.5	10	4	40.0	0.4	1028.9	1.0000	6.7	(-56.5,59.3)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.18	(0.35,4.15)	1.11	(0.52,3.13) (0.51,2.44)	
Sex					0.6912
Male	0.80	(0.05,29.23)	0.86	(0.16,22.08) (0.14,5.20)	
Female	1.50	(0.37,6.37)	1.29	(0.53,4.00) (0.54,3.07)	
Age					NC
>= 50 years	0.00	(0.00,3.27)	0.00	(0.00,5.12)	
< 50 years	2.13	(0.53,8.79)	1.52	(0.73,6.16) (0.69,3.35)	
Race					0.4714
Asian	1.75	(0.36,8.90)	1.42	(0.53,5.38) (0.53,3.81)	
White	0.69	(0.08,7.25)	0.79	(0.23,8.69) (0.22,2.79)	
Region					0.5283
Europe + Africa + US	0.75	(0.09,7.64)	0.83	(0.27,7.87) (0.24,2.86)	
Asia(ex Japan) + Japan	1.69	(0.33,8.97)	1.39	(0.49,5.07) (0.50,3.84)	
BMI					0.9875
< 25 kg/m2	1.09	(0.19,6.31)	1.05	(0.42,3.67) (0.42,2.61)	
25 to < 30 kg/m2	1.25	(0.08,43.86)	1.20	(0.12,32.40) (0.14,10.58)	
>= 30 kg/m2	1.33	(0.08,48.65)	1.20	(0.23,31.33) (0.20,7.05)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	3	60.0					
No	12	3	25.0			24	8	33.3					
Mutation status IL36RN after DNA resequencing													
Yes	6	3	50.0	0.1	3320.5	8	3	37.5	0.4	771.7	0.7347	-12.5	(-61.5,41.4)
No	11	2	18.2	0.3	624.4	21	8	38.1	0.7	1178.2	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore													
<4	12	5	41.7	0.2	2536.5	22	9	40.9	0.9	1011.5	1.0000	-0.8	(-35.9,33.2)
=4	6	1	16.7	0.2	450.9	13	4	30.8	0.4	890.9	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score													
=3	15	5	33.3	0.4	1323.4	28	11	39.3	1.0	1060.1	0.8304	6.0	(-26.4,34.8)
=4	3	1	33.3	0.0	2435.0	7	2	28.6	0.3	664.1	1.0000	-4.8	(-70.8,53.0)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	1	16.7					
No	15	6	40.0			29	12	41.4					
Background treatment prior to randomization													
Yes	8	2	25.0	0.2	1058.7	15	5	33.3	0.5	981.9	0.8321	8.3	(-36.0,44.4)
No	10	4	40.0	0.2	1739.3	20	8	40.0	0.8	964.4		0.0	(-38.9,35.9)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.2683
Yes	0.60	(0.06,5.96)	0.75	(0.18,3.12) (0.23,2.49)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					0.5625
<4	0.97	(0.22,4.34)	0.98	(0.42,3.03) (0.43,2.27)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					0.7724
=3	1.29	(0.34,5.19)	1.18	(0.51,4.16) (0.50,2.76)	
=4	0.80	(0.04,34.87)	0.86	(0.10,23.16) (0.12,6.23)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7369
Yes	1.50	(0.21,13.98)	1.33	(0.33,8.42) (0.33,5.39)	
No	1.00	(0.20,5.21)	1.00	(0.39,4.44) (0.39,2.53)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	6	37.5			34	13	38.2				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	6	33.3			32	12	37.5				
Renal impairment at baseline												
Normal	16	6	37.5			26	12	46.2				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	6	33.3	0.6	982.7	35	14	40.0	2.9	484.2	0.7741	6.7	(-22.7,32.9)
Sex													
Male	3	1	33.3	0.0	2282.8	14	6	42.9	1.3	459.4	1.0000	9.5	(-52.2,56.4)
Female	15	5	33.3	0.6	882.2	21	8	38.1	1.6	504.7	0.8933	4.8	(-28.4,35.8)
Age													
>= 50 years	4	1	25.0	0.1	1259.5	11	0	0.0	1.5	0.0	0.2576	-25.0	(-80.6,14.6)
< 50 years	14	5	35.7	0.5	941.4	24	14	58.3	1.4	985.3	0.2269	22.6	(-12.2,52.5)
Race													
Asian	13	4	30.8	0.5	741.6	16	8	50.0	1.4	568.5	0.4475	19.2	(-18.0,52.8)
White	5	2	40.0	0.1	2809.6	19	6	31.6	1.5	404.3	1.0000	-8.4	(-56.5,34.1)
Region													
Europe + Africa + US	5	2	40.0	0.1	2809.6	21	7	33.3	1.5	459.8	1.0000	-6.7	(-54.5,34.9)
Asia(ex Japan) + Japan	13	4	30.8	0.5	741.6	14	7	50.0	1.4	511.4	0.4965	19.2	(-19.4,55.4)
BMI													
< 25 kg/m2	9	4	44.4	0.2	1739.3	15	6	40.0	1.4	414.3	0.8961	-4.4	(-45.2,36.1)
25 to < 30 kg/m2	6	1	16.7	0.3	299.4	10	4	40.0	0.8	533.2	0.4435	23.3	(-29.5,64.1)
>= 30 kg/m2	3	1	33.3	0.0	2148.5	10	4	40.0	0.7	577.5	1.0000	6.7	(-56.5,59.3)

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.40,4.65)	1.20	(0.57,3.55) (0.56,2.59)	
Sex					0.9049
Male	1.50	(0.09,51.21)	1.29	(0.33,34.04) (0.23,7.11)	
Female	1.23	(0.30,5.29)	1.14	(0.46,3.47) (0.46,2.81)	
Age					NC
>= 50 years	0.00	(0.00,3.27)	0.00	(0.00,5.12)	
< 50 years	2.52	(0.63,10.44)	1.63	(0.80,7.34) (0.75,3.56)	
Race					0.3704
Asian	2.25	(0.47,11.33)	1.63	(0.63,7.11) (0.63,4.21)	
White	0.69	(0.08,7.25)	0.79	(0.23,8.69) (0.22,2.79)	
Region					0.4037
Europe + Africa + US	0.75	(0.09,7.64)	0.83	(0.27,7.87) (0.24,2.86)	
Asia(ex Japan) + Japan	2.25	(0.44,11.81)	1.63	(0.62,5.95) (0.62,4.28)	
BMI					0.6716
< 25 kg/m2	0.83	(0.15,4.89)	0.90	(0.32,3.23) (0.35,2.35)	
25 to < 30 kg/m2	3.33	(0.28,97.86)	2.40	(0.39,62.54) (0.34,16.76)	
>= 30 kg/m2	1.33	(0.08,48.65)	1.20	(0.23,31.33) (0.20,7.05)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	3	60.0					
No	12	3	25.0			24	9	37.5					
Mutation status IL36RN after DNA resequencing													
Yes	6	3	50.0	0.1	3320.5	8	3	37.5	1.0	300.2	0.7347	-12.5	(-61.5,41.4)
No	11	2	18.2	0.5	390.6	21	9	42.9	1.3	680.6	0.3134	24.7	(-12.2,53.2)
Baseline GPPGA pustulation subscore													
<4	12	5	41.7	0.2	2536.5	22	10	45.5	1.9	522.5	0.8853	3.8	(-31.9,37.6)
=4	6	1	16.7	0.4	241.9	13	4	30.8	1.0	409.2	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score													
=3	15	5	33.3	0.6	878.0	28	11	39.3	2.3	476.6	0.8304	6.0	(-26.4,34.8)
=4	3	1	33.3	0.0	2435.0	7	3	42.9	0.6	514.4	0.9428	9.5	(-58.8,65.2)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	2	33.3					
No	15	6	40.0			29	12	41.4					
Background treatment prior to randomization													
Yes	8	2	25.0	0.2	880.1	15	5	33.3	1.0	520.3	0.8321	8.3	(-36.0,44.4)
No	10	4	40.0	0.4	1043.6	20	9	45.0	1.9	466.3	0.9026	5.0	(-33.8,40.9)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.2136
Yes	0.60	(0.06,5.96)	0.75	(0.18,3.12) (0.23,2.49)	
No	3.38	(0.59,26.83)	2.36	(0.71,19.32) (0.61,9.07)	
Baseline GPPGA pustulation subscore					0.6278
<4	1.17	(0.27,5.18)	1.09	(0.48,3.28) (0.48,2.45)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					0.9322
=3	1.29	(0.34,5.19)	1.18	(0.51,4.16) (0.50,2.76)	
=4	1.50	(0.07,58.21)	1.29	(0.23,33.89) (0.21,7.89)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8412
Yes	1.50	(0.21,13.98)	1.33	(0.33,8.42) (0.33,5.39)	
No	1.23	(0.25,6.32)	1.13	(0.45,5.99) (0.46,2.77)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	6	37.5			34	14	41.2				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	6	33.3			32	13	40.6				
Renal impairment at baseline												
Normal	16	6	37.5			26	13	50.0				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.1.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	640.8	35	6	17.1	0.6	1014.6	0.7741	6.0	(-19.1,25.6)
Sex													
Male	3	0	0.0			14	3	21.4					
Female	15	2	13.3			21	3	14.3					
Age													
>= 50 years	4	1	25.0			11	4	36.4					
< 50 years	14	1	7.1			24	2	8.3					
Race													
Asian	13	2	15.4			16	0	0.0					
White	5	0	0.0			19	6	31.6					
Region													
Europe + Africa + US	5	0	0.0			21	6	28.6					
Asia(ex Japan) + Japan	13	2	15.4			14	0	0.0					
BMI													
< 25 kg/m2	9	2	22.2			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	3	30.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.66	(0.31,13.00)	1.54	(0.36,17.09) (0.35,6.89)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	2	40.0				
No	12	2	16.7			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	2	25.0				
No	11	2	18.2			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	4	18.2				
=4	6	1	16.7			13	2	15.4				
Baseline GPPGA score												
=3	15	2	13.3			28	5	17.9				
=4	3	0	0.0			7	1	14.3				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	2	33.3				
No	15	2	13.3			29	4	13.8				
Background treatment prior to randomization												
Yes	8	2	25.0			15	3	20.0				
No	10	0	0.0			20	3	15.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	2	12.5			34	6	17.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	2	11.1			32	5	15.6				
Renal impairment at baseline												
Normal	16	1	6.3			26	3	11.5				
Mild	1	1	100.0			6	2	33.3				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	459.4	35	6	17.1	1.7	358.1	0.7741	6.0	(-19.1,25.6)
Sex													
Male	3	0	0.0			14	3	21.4					
Female	15	2	13.3			21	3	14.3					
Age													
>= 50 years	4	1	25.0			11	4	36.4					
< 50 years	14	1	7.1			24	2	8.3					
Race													
Asian	13	2	15.4			16	0	0.0					
White	5	0	0.0			19	6	31.6					
Region													
Europe + Africa + US	5	0	0.0			21	6	28.6					
Asia(ex Japan) + Japan	13	2	15.4			14	0	0.0					
BMI													
< 25 kg/m2	9	2	22.2			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	3	30.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.66	(0.31,13.00)	1.54	(0.36,17.09) (0.35,6.89)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	2	40.0				
No	12	2	16.7			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	2	25.0				
No	11	2	18.2			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	4	18.2				
=4	6	1	16.7			13	2	15.4				
Baseline GPPGA score												
=3	15	2	13.3			28	5	17.9				
=4	3	0	0.0			7	1	14.3				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	2	33.3				
No	15	2	13.3			29	4	13.8				
Background treatment prior to randomization												
Yes	8	2	25.0			15	3	20.0				
No	10	0	0.0			20	3	15.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	2	12.5			34	6	17.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	2	11.1			32	5	15.6				
Renal impairment at baseline												
Normal	16	1	6.3			26	3	11.5				
Mild	1	1	100.0			6	2	33.3				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.7	269.6	35	6	17.1	4.3	139.6	0.7741	6.0	(-19.1,25.6)
Sex													
Male	3	0	0.0			14	3	21.4					
Female	15	2	13.3			21	3	14.3					
Age													
>= 50 years	4	1	25.0			11	4	36.4					
< 50 years	14	1	7.1			24	2	8.3					
Race													
Asian	13	2	15.4			16	0	0.0					
White	5	0	0.0			19	6	31.6					
Region													
Europe + Africa + US	5	0	0.0			21	6	28.6					
Asia(ex Japan) + Japan	13	2	15.4			14	0	0.0					
BMI													
< 25 kg/m2	9	2	22.2			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	3	30.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.66	(0.31,13.00)	1.54	(0.36,17.09) (0.35,6.89)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	2	40.0				
No	12	2	16.7			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	2	25.0				
No	11	2	18.2			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	4	18.2				
=4	6	1	16.7			13	2	15.4				
Baseline GPPGA score												
=3	15	2	13.3			28	5	17.9				
=4	3	0	0.0			7	1	14.3				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	2	33.3				
No	15	2	13.3			29	4	13.8				
Background treatment prior to randomization												
Yes	8	2	25.0			15	3	20.0				
No	10	0	0.0			20	3	15.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 12 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	2	12.5			34	6	17.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	2	11.1			32	5	15.6				
Renal impairment at baseline												
Normal	16	1	6.3			26	3	11.5				
Mild	1	1	100.0			6	2	33.3				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity overall and by subgroup up to week 12 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Overall	18	0	0.0			35	0	0.0				
Sex												
Male	3	0	0.0			14	0	0.0				
Female	15	0	0.0			21	0	0.0				
Age												
>= 50 years	4	0	0.0			11	0	0.0				
< 50 years	14	0	0.0			24	0	0.0				
Race												
Asian	13	0	0.0			16	0	0.0				
White	5	0	0.0			19	0	0.0				
Region												
Europe + Africa + US	5	0	0.0			21	0	0.0				
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0				
BMI												
< 25 kg/m2	9	0	0.0			15	0	0.0				
25 to < 30 kg/m2	6	0	0.0			10	0	0.0				
>= 30 kg/m2	3	0	0.0			10	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall				
Sex				
Male				
Female				
Age				
>= 50 years				
< 50 years				
Race				
Asian				
White				
Region				
Europe + Africa + US				
Asia(ex Japan) + Japan				
BMI				
< 25 kg/m2				
25 to < 30 kg/m2				
>= 30 kg/m2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	0	0.0				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	0	0.0				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	0	0.0				
Baseline GPPGA score												
=3	15	0	0.0			28	0	0.0				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	0	0.0				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	0	0.0				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	0	0.0				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Overall	18	0	0.0			35	0	0.0				
Sex												
Male	3	0	0.0			14	0	0.0				
Female	15	0	0.0			21	0	0.0				
Age												
>= 50 years	4	0	0.0			11	0	0.0				
< 50 years	14	0	0.0			24	0	0.0				
Race												
Asian	13	0	0.0			16	0	0.0				
White	5	0	0.0			19	0	0.0				
Region												
Europe + Africa + US	5	0	0.0			21	0	0.0				
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0				
BMI												
< 25 kg/m2	9	0	0.0			15	0	0.0				
25 to < 30 kg/m2	6	0	0.0			10	0	0.0				
>= 30 kg/m2	3	0	0.0			10	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall				
Sex				
Male				
Female				
Age				
>= 50 years				
< 50 years				
Race				
Asian				
White				
Region				
Europe + Africa + US				
Asia(ex Japan) + Japan				
BMI				
< 25 kg/m2				
25 to < 30 kg/m2				
>= 30 kg/m2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	0	0.0				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	0	0.0				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	0	0.0				
Baseline GPPGA score												
=3	15	0	0.0			28	0	0.0				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	0	0.0				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN			
Yes			
No			
Mutation status IL36RN after DNA resequencing			
Yes			
No			
Baseline GPPGA pustulation subscore			
<4			
=4			
Baseline GPPGA score			
=3			
=4			
Baseline plaque psoriasis			
Yes			
No			
Background treatment prior to randomization			
Yes			
No			

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	0	0.0				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	0	0.0				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	5.0	19.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	0	0.0					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	0	0.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.1.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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1.1.2 Adverse events excluding disease-specific adverse events

Table 1.2.1 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	10	55.6	0.2	4623.4	35	23	65.7	0.4	5874.7	0.7606	10.2	(-17.4,38.2)
Sex													
Male	3	1	33.3	0.0	2435.0	14	10	71.4	0.2	6190.7	0.3501	38.1	(-24.2,80.4)
Female	15	9	60.0	0.2	5136.3	21	13	61.9	0.2	5652.7	0.9518	1.9	(-30.2,35.1)
Age													
>= 50 years	4	4	100.0	0.0	16233.3	11	7	63.6	0.1	5558.2	0.2581	-36.4	(-69.2,26.6)
< 50 years	14	6	42.9	0.2	3130.7	24	16	66.7	0.3	6024.7	0.1793	23.8	(-10.4,53.9)
Race													
Asian	13	8	61.5	0.1	5513.2	16	11	68.8	0.2	6809.7	0.8074	7.2	(-30.0,42.4)
White	5	2	40.0	0.1	2809.6	19	12	63.2	0.2	5217.9	0.5151	23.2	(-25.8,63.9)
Region													
Europe + Africa + US	5	2	40.0	0.1	2809.6	21	14	66.7	0.2	5877.6	0.3830	26.7	(-22.2,66.4)
Asia(ex Japan) + Japan	13	8	61.5	0.1	5513.2	14	9	64.3	0.2	5870.1	0.9877	2.7	(-34.9,39.4)
BMI													
< 25 kg/m2	9	7	77.8	0.1	8247.6	15	7	46.7	0.2	3759.9	0.1781	-31.1	(-64.1,11.7)
25 to < 30 kg/m2	6	2	33.3	0.1	2213.6	10	8	80.0	0.1	8348.6	0.0959	46.7	(-6.5,83.0)
>= 30 kg/m2	3	1	33.3	0.0	2435.0	10	8	80.0	0.1	7305.0	0.2291	46.7	(-19.3,90.5)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.1 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.53	(0.46,5.00)	1.18	(0.75,2.17) (0.73,1.91)	
Sex					0.4046
Male	5.00	(0.28,160.77)	2.14	(0.68,62.55) (0.42,10.98)	
Female	1.08	(0.26,4.36)	1.03	(0.60,2.18) (0.61,1.76)	
Age					0.0292
>= 50 years	0.00	(0.00,1.98)	0.64	(0.31,1.76) (0.41,0.99)	
< 50 years	2.67	(0.66,10.79)	1.56	(0.85,4.59) (0.80,3.03)	
Race					0.5877
Asian	1.38	(0.28,6.79)	1.12	(0.60,2.44) (0.65,1.92)	
White	2.57	(0.30,25.16)	1.58	(0.64,14.26) (0.51,4.87)	
Region					0.4665
Europe + Africa + US	3.00	(0.35,28.95)	1.67	(0.69,18.41) (0.55,5.08)	
Asia(ex Japan) + Japan	1.13	(0.22,5.73)	1.04	(0.53,2.21) (0.58,1.87)	
BMI					0.0612
< 25 kg/m2	0.25	(0.03,1.66)	0.60	(0.27,1.31) (0.32,1.14)	
25 to < 30 kg/m2	8.00	(0.71,91.50)	2.40	(0.90,19.53) (0.74,7.76)	
>= 30 kg/m2	8.00	(0.35,261.87)	2.40	(0.76,71.17) (0.47,12.25)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.1 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	3	60.0					
No	12	6	50.0			24	15	62.5					
Mutation status IL36RN after DNA resequencing													
Yes	6	4	66.7	0.1	6957.1	8	5	62.5	0.1	5072.9	0.9864	-4.2	(-54.1,48.1)
No	11	5	45.5	0.2	3203.9	21	13	61.9	0.2	5521.2	0.4405	16.5	(-21.0,51.6)
Baseline GPPGA pustulation subscore													
<4	12	8	66.7	0.1	5963.3	22	14	63.6	0.2	6087.5	0.9231	-3.0	(-35.4,32.9)
=4	6	2	33.3	0.1	2435.0	13	9	69.2	0.2	5571.6	0.2821	35.9	(-15.7,73.7)
Baseline GPPGA score													
=3	15	9	60.0	0.2	5136.3	28	19	67.9	0.3	6366.7	0.7551	7.9	(-22.0,38.8)
=4	3	1	33.3	0.0	2435.0	7	4	57.1	0.1	4297.1	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	4	66.7					
No	15	10	66.7			29	19	65.5					
Background treatment prior to randomization													
Yes	8	5	62.5	0.1	5534.1	15	10	66.7	0.1	6763.9	0.9080	4.2	(-35.9,46.6)
No	10	5	50.0	0.1	3970.1	20	13	65.0	0.2	5335.1	0.4911	15.0	(-23.0,51.1)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.1 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.4930
Yes	0.83	(0.07,8.69)	0.94	(0.35,2.79) (0.43,2.04)	
No	1.95	(0.42,9.05)	1.36	(0.69,5.09) (0.66,2.82)	
Baseline GPPGA pustulation subscore					0.2386
<4	0.88	(0.18,3.96)	0.95	(0.57,1.83) (0.57,1.59)	
=4	4.50	(0.52,44.07)	2.08	(0.78,15.12) (0.63,6.81)	
Baseline GPPGA score					0.6490
=3	1.41	(0.36,5.30)	1.13	(0.71,2.17) (0.70,1.84)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6834
Yes	1.20	(0.17,7.63)	1.07	(0.56,2.85) (0.56,2.03)	
No	1.86	(0.37,9.18)	1.30	(0.68,4.69) (0.65,2.61)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.1 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	8	50.0			34	23	67.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	10	55.6			32	20	62.5				
Renal impairment at baseline												
Normal	16	8	50.0			26	16	61.5				
Mild	1	1	100.0			6	5	83.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.1 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.2 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	11	61.1	0.3	3939.0	35	24	68.6	0.8	3164.6	0.7741	7.5	(-19.5,36.0)
Sex													
Male	3	2	66.7	0.0	4565.6	14	10	71.4	0.3	2922.0	1.0000	4.8	(-42.6,64.8)
Female	15	9	60.0	0.2	3822.4	21	14	66.7	0.4	3364.1	0.7368	6.7	(-25.4,39.0)
Age													
>= 50 years	4	4	100.0	0.0	16233.3	11	7	63.6	0.2	2840.8	0.2581	-36.4	(-69.2,26.6)
< 50 years	14	7	50.0	0.3	2749.2	24	17	70.8	0.5	3320.5	0.3430	20.8	(-12.2,51.6)
Race													
Asian	13	9	69.2	0.2	4325.3	16	11	68.8	0.4	2733.2	1.0000	-0.5	(-36.3,36.3)
White	5	2	40.0	0.1	2809.6	19	13	68.4	0.4	3652.5	0.3193	28.4	(-20.3,68.4)
Region													
Europe + Africa + US	5	2	40.0	0.1	2809.6	21	15	71.4	0.4	4119.4	0.2273	31.4	(-17.1,71.6)
Asia(ex Japan) + Japan	13	9	69.2	0.2	4325.3	14	9	64.3	0.4	2282.8	0.8881	-4.9	(-40.7,31.7)
BMI													
< 25 kg/m2	9	7	77.8	0.1	8247.6	15	8	53.3	0.4	1849.4	0.3501	-24.4	(-58.5,18.9)
25 to < 30 kg/m2	6	3	50.0	0.2	1956.7	10	8	80.0	0.2	3698.7	0.3511	30.0	(-20.4,72.9)
>= 30 kg/m2	3	1	33.3	0.0	2435.0	10	8	80.0	0.1	7305.0	0.2291	46.7	(-19.3,90.5)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.2 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.39	(0.40,4.62)	1.12	(0.75,2.01) (0.73,1.73)	
Sex					0.9435
Male	1.25	(0.03,20.55)	1.07	(0.53,11.61) (0.45,2.55)	
Female	1.33	(0.32,5.47)	1.11	(0.66,2.19) (0.67,1.85)	
Age					0.0328
>= 50 years	0.00	(0.00,1.98)	0.64	(0.31,1.76) (0.41,0.99)	
< 50 years	2.43	(0.59,9.89)	1.42	(0.82,3.27) (0.79,2.54)	
Race					0.3820
Asian	0.98	(0.18,5.05)	0.99	(0.57,1.91) (0.61,1.62)	
White	3.25	(0.37,31.86)	1.71	(0.71,14.26) (0.56,5.22)	
Region					0.2968
Europe + Africa + US	3.75	(0.43,36.32)	1.79	(0.76,18.41) (0.59,5.40)	
Asia(ex Japan) + Japan	0.80	(0.15,4.25)	0.93	(0.49,1.74) (0.55,1.58)	
BMI					0.1475
< 25 kg/m2	0.33	(0.04,2.17)	0.69	(0.34,1.52) (0.38,1.23)	
25 to < 30 kg/m2	4.00	(0.37,44.70)	1.60	(0.71,8.56) (0.68,3.77)	
>= 30 kg/m2	8.00	(0.35,261.87)	2.40	(0.76,71.17) (0.47,12.25)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.2.2 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	4	80.0					
No	12	6	50.0			24	15	62.5					
Mutation status IL36RN after DNA resequencing													
Yes	6	4	66.7	0.1	6957.1	8	6	75.0	0.2	2672.6	0.8565	8.3	(-43.9,57.7)
No	11	6	54.5	0.2	2739.4	21	13	61.9	0.4	3123.8	0.8409	7.4	(-28.4,43.2)
Baseline GPPGA pustulation subscore													
<4	12	8	66.7	0.1	5963.3	22	15	68.2	0.5	3148.7	1.0000	1.5	(-30.3,37.1)
=4	6	3	50.0	0.1	2067.5	13	9	69.2	0.3	3191.5	0.5245	19.2	(-28.1,64.1)
Baseline GPPGA score													
=3	15	10	66.7	0.2	4198.3	28	20	71.4	0.6	3305.4	0.8419	4.8	(-23.5,36.1)
=4	3	1	33.3	0.0	2435.0	7	4	57.1	0.2	2608.9	0.8467	23.8	(-47.1,76.0)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	4	66.7					
No	15	10	66.7			29	20	69.0					
Background treatment prior to randomization													
Yes	8	5	62.5	0.1	5534.1	15	10	66.7	0.3	3727.0	0.9080	4.2	(-35.9,46.6)
No	10	6	60.0	0.2	3176.1	20	14	70.0	0.5	2856.7	0.7850	10.0	(-25.7,47.7)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.2 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.9854
Yes	1.50	(0.11,19.29)	1.13	(0.50,3.26) (0.56,2.25)	
No	1.35	(0.29,6.20)	1.13	(0.60,2.89) (0.60,2.14)	
Baseline GPPGA pustulation subscore					0.5552
<4	1.07	(0.22,4.94)	1.02	(0.62,2.05) (0.63,1.67)	
=4	2.25	(0.26,18.28)	1.38	(0.62,6.66) (0.58,3.33)	
Baseline GPPGA score					0.6041
=3	1.25	(0.30,4.93)	1.07	(0.70,1.90) (0.70,1.64)	
=4	2.67	(0.13,97.01)	1.71	(0.35,46.07) (0.31,9.61)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.8398
Yes	1.20	(0.17,7.63)	1.07	(0.56,2.85) (0.56,2.03)	
No	1.56	(0.29,7.94)	1.17	(0.67,2.79) (0.65,2.09)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.2 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	9	56.3			34	24	70.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	11	61.1			32	21	65.6				
Renal impairment at baseline												
Normal	16	9	56.3			26	17	65.4				
Mild	1	1	100.0			6	5	83.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.2 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.3 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	11	61.1	0.4	2542.9	35	26	74.3	1.6	1626.1	0.4283	13.2	(-13.3,41.4)
Sex													
Male	3	2	66.7	0.0	4565.6	14	12	85.7	0.7	1654.0	0.6084	19.0	(-27.4,76.5)
Female	15	9	60.0	0.4	2315.0	21	14	66.7	0.9	1603.0	0.7368	6.7	(-25.4,39.0)
Age													
>= 50 years	4	4	100.0	0.0	16233.3	11	7	63.6	0.6	1265.7	0.2581	-36.4	(-69.2,26.6)
< 50 years	14	7	50.0	0.4	1715.9	24	19	79.2	1.0	1816.7	0.0997	29.2	(-2.8,58.6)
Race													
Asian	13	9	69.2	0.4	2490.3	16	12	75.0	1.0	1214.1	0.8076	5.8	(-28.6,40.2)
White	5	2	40.0	0.1	2809.6	19	14	73.7	0.6	2293.0	0.2115	33.7	(-14.9,72.8)
Region													
Europe + Africa + US	5	2	40.0	0.1	2809.6	21	16	76.2	0.6	2585.8	0.1850	36.2	(-11.4,74.5)
Asia(ex Japan) + Japan	13	9	69.2	0.4	2490.3	14	10	71.4	1.0	1020.3	1.0000	2.2	(-33.5,37.6)
BMI													
< 25 kg/m2	9	7	77.8	0.1	8247.6	15	9	60.0	1.0	905.6	0.4783	-17.8	(-52.3,25.7)
25 to < 30 kg/m2	6	3	50.0	0.3	978.3	10	9	90.0	0.5	1816.2	0.1402	40.0	(-10.6,80.0)
>= 30 kg/m2	3	1	33.3	0.0	2435.0	10	8	80.0	0.1	7305.0	0.2291	46.7	(-19.3,90.5)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.3 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.84	(0.52,6.31)	1.22	(0.83,2.12) (0.80,1.84)	
Sex					0.7689
Male	3.00	(0.07,55.70)	1.29	(0.71,11.61) (0.56,2.94)	
Female	1.33	(0.32,5.47)	1.11	(0.66,2.19) (0.67,1.85)	
Age					0.0129
>= 50 years	0.00	(0.00,1.98)	0.64	(0.31,1.76) (0.41,0.99)	
< 50 years	3.80	(0.86,16.81)	1.58	(0.96,3.80) (0.90,2.78)	
Race					0.3852
Asian	1.33	(0.24,7.42)	1.08	(0.65,2.09) (0.68,1.72)	
White	4.20	(0.46,41.47)	1.84	(0.79,20.36) (0.61,5.57)	
Region					0.3184
Europe + Africa + US	4.80	(0.53,46.89)	1.90	(0.82,18.41) (0.63,5.72)	
Asia(ex Japan) + Japan	1.11	(0.19,6.33)	1.03	(0.57,1.89) (0.63,1.69)	
BMI					0.1446
< 25 kg/m2	0.43	(0.05,2.88)	0.77	(0.41,1.76) (0.45,1.33)	
25 to < 30 kg/m2	9.00	(0.60,260.11)	1.80	(0.86,8.56) (0.79,4.11)	
>= 30 kg/m2	8.00	(0.35,261.87)	2.40	(0.76,71.17) (0.47,12.25)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.3 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	4	80.0					
No	12	6	50.0			24	16	66.7					
Mutation status IL36RN after DNA resequencing													
Yes	6	4	66.7	0.1	6957.1	8	6	75.0	0.5	1129.6	0.8565	8.3	(-43.9,57.7)
No	11	6	54.5	0.4	1611.4	21	14	66.7	0.8	1649.5	0.7641	12.1	(-23.7,47.5)
Baseline GPPGA pustulation subscore													
<4	12	8	66.7	0.1	5963.3	22	16	72.7	1.0	1546.0	0.8250	6.1	(-25.5,41.1)
=4	6	3	50.0	0.3	1005.3	13	10	76.9	0.6	1773.1	0.3332	26.9	(-19.8,69.5)
Baseline GPPGA score													
=3	15	10	66.7	0.4	2554.2	28	21	75.0	1.3	1594.6	0.7551	8.3	(-19.7,39.3)
=4	3	1	33.3	0.0	2435.0	7	5	71.4	0.3	1773.1	0.3817	38.1	(-32.0,85.4)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	5	83.3					
No	15	10	66.7			29	21	72.4					
Background treatment prior to randomization													
Yes	8	5	62.5	0.1	5534.1	15	10	66.7	0.6	1739.3	0.9080	4.2	(-35.9,46.6)
No	10	6	60.0	0.3	1753.2	20	16	80.0	1.0	1562.6	0.3645	20.0	(-14.9,56.3)

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.3 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.8611
Yes	1.50	(0.11,19.29)	1.13	(0.50,3.26) (0.56,2.25)	
No	1.67	(0.35,7.75)	1.22	(0.68,3.03) (0.66,2.27)	
Baseline GPPGA pustulation subscore					0.4904
<4	1.33	(0.26,6.34)	1.09	(0.67,2.15) (0.68,1.75)	
=4	3.33	(0.36,28.95)	1.54	(0.74,6.67) (0.66,3.61)	
Baseline GPPGA score					0.4625
=3	1.50	(0.35,6.08)	1.13	(0.75,2.05) (0.74,1.71)	
=4	5.00	(0.21,174.36)	2.14	(0.53,60.12) (0.40,11.35)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6063
Yes	1.20	(0.17,7.63)	1.07	(0.56,2.85) (0.56,2.03)	
No	2.67	(0.45,15.20)	1.33	(0.81,3.48) (0.77,2.31)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.3 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	9	56.3			34	26	76.5				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	11	61.1			32	23	71.9				
Renal impairment at baseline												
Normal	16	9	56.3			26	19	73.1				
Mild	1	1	100.0			6	5	83.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.3 Proportion and incidence rate of patients with any adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.4 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	2	5.7	0.6	309.5	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	1	9.1					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.4 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.4 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	1	20.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	1	12.5				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.4 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.4 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.4 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.5 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.8	110.7	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	1	9.1					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.5 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.5 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	1	20.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	1	12.5				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.5 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.5 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.5 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.6 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	3	8.6	4.6	65.6	0.3121	8.6	(-11.7,23.1)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	2	9.5					
Age													
>= 50 years	4	0	0.0			11	1	9.1					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	2	10.5					
Region													
Europe + Africa + US	5	0	0.0			21	2	9.5					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.6 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.45, inf)	inf	(0.36, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.6 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	1	20.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	1	12.5				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	0	0.0			28	3	10.7				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	3	10.3				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	3	15.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.6 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.6 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	3	8.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	2	7.7				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.6 Proportion and incidence rate of patients with serious adverse events excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	4	22.2	0.3	1365.4	35	14	40.0	0.5	2856.7	0.3094	17.8	(-11.7,41.6)
Sex													
Male	3	0	0.0	0.1	0.0	14	7	50.0	0.2	3601.1	0.1596	50.0	(-19.1,77.0)
Female	15	4	26.7	0.2	1698.8	21	7	33.3	0.3	2367.4	0.7368	6.7	(-26.3,36.6)
Age													
>= 50 years	4	4	100.0	0.0	16233.3	11	3	27.3	0.2	1857.2	0.0460	-72.7	(-94.0,-0.7)
< 50 years	14	0	0.0	0.3	0.0	24	11	45.8	0.3	3348.1	0.0026	45.8	(17.5,67.2)
Race													
Asian	13	4	30.8	0.2	2029.2	16	8	50.0	0.2	4058.3	0.4475	19.2	(-18.0,52.8)
White	5	0	0.0	0.1	0.0	19	6	31.6	0.3	2048.1	0.2080	31.6	(-23.9,57.0)
Region													
Europe + Africa + US	5	0	0.0	0.1	0.0	21	8	38.1	0.3	2656.4	0.1849	38.1	(-15.1,62.8)
Asia(ex Japan) + Japan	13	4	30.8	0.2	2029.2	14	6	42.9	0.2	3176.1	0.6332	12.1	(-25.6,47.9)
BMI													
< 25 kg/m2	9	2	22.2			15	5	33.3					
25 to < 30 kg/m2	6	2	33.3			10	5	50.0					
>= 30 kg/m2	3	0	0.0			10	4	40.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.33	(0.64,9.60)	1.80	(0.75,7.64) (0.69,4.68)	
Sex					NC
Male	inf	(0.66, inf)	inf	(0.66, inf)	
Female	1.38	(0.31,6.56)	1.25	(0.43,5.11) (0.44,3.52)	
Age					NC
>= 50 years	0.00	(0.00,0.48)	0.27	(0.06,0.96) (0.10,0.72)	
< 50 years	inf	(3.79, inf)	inf	(1.72, inf)	
Race					NC
Asian	2.25	(0.47,11.33)	1.63	(0.63,7.11) (0.63,4.21)	
White	inf	(0.62, inf)	inf	(0.54, inf)	
Region					NC
Europe + Africa + US	inf	(0.85, inf)	inf	(0.69, inf)	
Asia(ex Japan) + Japan	1.69	(0.33,8.97)	1.39	(0.49,5.07) (0.50,3.84)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	0	0.0			5	1	20.0					
No	12	2	16.7			24	10	41.7					
Mutation status IL36RN after DNA resequencing													
Yes	6	2	33.3	0.1	2356.5	8	3	37.5	0.1	2883.6	0.9864	4.2	(-48.1,54.1)
No	11	2	18.2	0.2	1058.7	21	8	38.1	0.3	2705.6	0.3829	19.9	(-18.4,48.6)
Baseline GPPGA pustulation subscore													
<4	12	4	33.3	0.2	2247.7	22	8	36.4	0.3	2680.7	0.9231	3.0	(-32.9,35.4)
=4	6	0	0.0	0.1	0.0	13	6	46.2	0.2	3130.7	0.0850	46.2	(-4.3,74.9)
Baseline GPPGA score													
=3	15	4	26.7	0.2	1698.8	28	10	35.7	0.4	2519.0	0.7551	9.0	(-22.8,36.1)
=4	3	0	0.0	0.1	0.0	7	4	57.1	0.1	4297.1	0.1336	57.1	(-22.9,90.5)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	3	50.0					
No	15	4	26.7			29	11	37.9					
Background treatment prior to randomization													
Yes	8	2	25.0			15	7	46.7					
No	10	2	20.0			20	7	35.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					0.5397
Yes	1.20	(0.12,14.32)	1.13	(0.23,10.57) (0.27,4.76)	
No	2.77	(0.48,22.31)	2.10	(0.60,17.31) (0.53,8.22)	
Baseline GPPGA pustulation subscore					NC
<4	1.14	(0.25,5.58)	1.09	(0.41,5.13) (0.41,2.89)	
=4	inf	(1.29, inf)	inf	(0.95, inf)	
Baseline GPPGA score					NC
=3	1.53	(0.38,6.78)	1.34	(0.53,7.80) (0.51,3.55)	
=4	inf	(0.68, inf)	inf	(0.67, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	2	12.5			34	14	41.2				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	4	22.2			32	13	40.6				
Renal impairment at baseline												
Normal	16	2	12.5			26	11	42.3				
Mild	1	1	100.0			6	2	33.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.8 Proportion and incidence rate of patients withadverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	4	22.2	0.5	811.7	35	10	28.6	1.6	608.8	0.7741	6.3	(-21.3,29.6)
Sex													
Male	3	1	33.3			14	6	42.9					
Female	15	3	20.0			21	4	19.0					
Age													
>= 50 years	4	3	75.0			11	3	27.3					
< 50 years	14	1	7.1			24	7	29.2					
Race													
Asian	13	4	30.8	0.4	1007.6	16	6	37.5	0.8	791.2	0.8076	6.7	(-30.0,42.4)
White	5	0	0.0	0.1	0.0	19	4	21.1	0.9	452.3	0.3657	21.1	(-31.7,46.8)
Region													
Europe + Africa + US	5	0	0.0			21	6	28.6					
Asia(ex Japan) + Japan	13	4	30.8			14	4	28.6					
BMI													
< 25 kg/m2	9	2	22.2			15	4	26.7					
25 to < 30 kg/m2	6	2	33.3			10	5	50.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.8 Proportion and incidence rate of patients withadverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.40	(0.37,5.96)	1.29	(0.48,7.59) (0.47,3.53)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					NC
Asian	1.35	(0.27,7.01)	1.22	(0.41,4.47) (0.43,3.42)	
White	inf	(0.34, inf)	inf	(0.32, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.8 Proportion and incidence rate of patients withadverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	0	0.0			5	0	0.0					
No	12	2	16.7			24	8	33.3					
Mutation status IL36RN after DNA resequencing													
Yes	6	1	16.7			8	2	25.0					
No	11	3	27.3			21	6	28.6					
Baseline GPPGA pustulation subscore													
<4	12	3	25.0			22	5	22.7					
=4	6	1	16.7			13	5	38.5					
Baseline GPPGA score													
=3	15	4	26.7	0.4	918.9	28	7	25.0	1.4	490.7	0.9616	-1.7	(-32.2,24.9)
=4	3	0	0.0	0.1	0.0	7	3	42.9	0.2	1387.0	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	2	33.3					
No	15	3	20.0			29	8	27.6					
Background treatment prior to randomization													
Yes	8	2	25.0			15	5	33.3					
No	10	2	20.0			20	5	25.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.8 Proportion and incidence rate of patients withadverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	0.92	(0.22,4.29)	0.94	(0.32,4.04) (0.33,2.70)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.8 Proportion and incidence rate of patients withadverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	2	12.5			34	10	29.4				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	4	22.2			32	9	28.1				
Renal impairment at baseline												
Normal	16	2	12.5			26	7	26.9				
Mild	1	1	100.0			6	2	33.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.8 Proportion and incidence rate of patients withadverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	4	22.2	0.8	477.5	35	10	28.6	4.4	225.9	0.7741	6.3	(-21.3,29.6)
Sex													
Male	3	1	33.3			14	6	42.9					
Female	15	3	20.0			21	4	19.0					
Age													
>= 50 years	4	3	75.0			11	3	27.3					
< 50 years	14	1	7.1			24	7	29.2					
Race													
Asian	13	4	30.8	0.7	539.1	16	6	37.5	2.1	281.0	0.8076	6.7	(-30.0,42.4)
White	5	0	0.0	0.1	0.0	19	4	21.1	2.3	174.6	0.3657	21.1	(-31.7,46.8)
Region													
Europe + Africa + US	5	0	0.0			21	6	28.6					
Asia(ex Japan) + Japan	13	4	30.8			14	4	28.6					
BMI													
< 25 kg/m2	9	2	22.2			15	5	33.3					
25 to < 30 kg/m2	6	2	33.3			10	4	40.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.40	(0.37,5.96)	1.29	(0.48,7.59) (0.47,3.53)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					NC
Asian	1.35	(0.27,7.01)	1.22	(0.41,4.47) (0.43,3.42)	
White	inf	(0.34, inf)	inf	(0.32, inf)	
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	0	0.0			5	0	0.0					
No	12	2	16.7			24	7	29.2					
Mutation status IL36RN after DNA resequencing													
Yes	6	1	16.7			8	2	25.0					
No	11	3	27.3			21	5	23.8					
Baseline GPPGA pustulation subscore													
<4	12	3	25.0			22	5	22.7					
=4	6	1	16.7			13	5	38.5					
Baseline GPPGA score													
=3	15	4	26.7	0.8	512.6	28	7	25.0	3.9	179.3	0.9616	-1.7	(-32.2,24.9)
=4	3	0	0.0	0.1	0.0	7	3	42.9	0.5	573.7	0.2974	42.9	(-34.3,81.6)
Baseline plaque psoriasis													
Yes	3	1	33.3			6	2	33.3					
No	15	3	20.0			29	8	27.6					
Background treatment prior to randomization													
Yes	8	2	25.0			15	5	33.3					
No	10	2	20.0			20	5	25.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	0.92	(0.22,4.29)	0.94	(0.32,4.04) (0.33,2.70)	
=4	inf	(0.39, inf)	inf	(0.42, inf)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	2	100.0			1	0	0.0				
> 40	16	2	12.5			34	10	29.4				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	4	22.2			32	9	28.1				
Renal impairment at baseline												
Normal	16	2	12.5			26	7	26.9				
Mild	1	1	100.0			6	2	33.3				
Moderate	0	0	na			1	1	100.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.3	1675.5	35	7	20.0	0.6	1206.0	0.7740	-7.8	(-34.8,15.9)
Sex													
Male	3	1	33.3			14	2	14.3					
Female	15	4	26.7			21	5	23.8					
Age													
>= 50 years	4	0	0.0			11	3	27.3					
< 50 years	14	5	35.7			24	4	16.7					
Race													
Asian	13	3	23.1			16	3	18.8					
White	5	2	40.0			19	4	21.1					
Region													
Europe + Africa + US	5	2	40.0			21	4	19.0					
Asia(ex Japan) + Japan	13	3	23.1			14	3	21.4					
BMI													
< 25 kg/m2	9	4	44.4			15	2	13.3					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	1	33.3			10	3	30.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.17,2.65)	0.72	(0.26,2.17) (0.27,1.95)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	1	20.0					
No	12	3	25.0			24	4	16.7					
Mutation status IL36RN after DNA resequencing													
Yes	6	2	33.3			8	1	12.5					
No	11	2	18.2			21	4	19.0					
Baseline GPPGA pustulation subscore													
<4	12	4	33.3			22	4	18.2					
=4	6	1	16.7			13	3	23.1					
Baseline GPPGA score													
=3	15	4	26.7	0.3	1554.3	28	7	25.0	0.4	1568.6	0.9616	-1.7	(-32.2,24.9)
=4	3	1	33.3	0.0	2435.0	7	0	0.0	0.1	0.0	0.2974	-33.3	(-90.6,22.4)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	1	16.7					
No	15	5	33.3			29	6	20.7					
Background treatment prior to randomization													
Yes	8	2	25.0			15	3	20.0					
No	10	3	30.0			20	4	20.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					
<4					
=4					
Baseline GPPGA score					NC
=3	0.92	(0.22,4.29)	0.94	(0.32,4.04) (0.33,2.70)	
=4	0.00	(0.00,3.86)	0.00	(0.00,5.95)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					
Yes					
No					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	5	31.3			34	7	20.6				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	5	27.8			32	5	15.6				
Renal impairment at baseline												
Normal	16	5	31.3			26	4	15.4				
Mild	1	0	0.0			6	3	50.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	6	33.3	0.4	1413.9	35	12	34.3	1.3	889.0	1.0000	1.0	(-27.6,27.0)
Sex													
Male	3	1	33.3	0.0	2282.8	14	3	21.4	0.7	452.8	1.0000	-11.9	(-70.8,35.2)
Female	15	5	33.3	0.4	1313.8	21	9	42.9	0.7	1309.7	0.6757	9.5	(-24.0,40.5)
Age													
>= 50 years	4	1	25.0	0.1	1259.5	11	3	27.3	0.4	735.4	1.0000	2.3	(-55.5,46.5)
< 50 years	14	5	35.7	0.3	1449.4	24	9	37.5	0.9	955.6	1.0000	1.8	(-31.5,32.6)
Race													
Asian	13	4	30.8			16	5	31.3					
White	5	2	40.0			19	7	36.8					
Region													
Europe + Africa + US	5	2	40.0			21	7	33.3					
Asia(ex Japan) + Japan	13	4	30.8			14	5	35.7					
BMI													
< 25 kg/m2	9	4	44.4			15	4	26.7					
25 to < 30 kg/m2	6	1	16.7			10	2	20.0					
>= 30 kg/m2	3	1	33.3			10	6	60.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.04	(0.31,3.69)	1.03	(0.47,2.95) (0.46,2.29)	
Sex					0.5135
Male	0.55	(0.03,21.23)	0.64	(0.10,16.64) (0.10,4.25)	
Female	1.50	(0.37,6.37)	1.29	(0.53,4.00) (0.54,3.07)	
Age					0.9721
>= 50 years	1.13	(0.08,39.00)	1.09	(0.16,28.32) (0.15,7.69)	
< 50 years	1.08	(0.27,4.58)	1.05	(0.43,3.27) (0.44,2.51)	
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	3	60.0					
No	12	3	25.0			24	6	25.0					
Mutation status IL36RN after DNA resequencing													
Yes	6	3	50.0			8	3	37.5					
No	11	2	18.2			21	6	28.6					
Baseline GPPGA pustulation subscore													
<4	12	5	41.7	0.2	2467.9	22	8	36.4	0.9	901.9	0.8250	-5.3	(-40.1,28.6)
=4	6	1	16.7	0.2	450.9	13	4	30.8	0.5	864.5	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score													
=3	15	5	33.3	0.4	1304.5	28	11	39.3	1.0	1062.9	0.8304	6.0	(-26.4,34.8)
=4	3	1	33.3	0.0	2435.0	7	1	14.3	0.3	317.6	0.8467	-19.0	(-79.3,39.0)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	2	33.3					
No	15	6	40.0			29	10	34.5					
Background treatment prior to randomization													
Yes	8	2	25.0	0.2	1058.7	15	5	33.3	0.5	1014.6	0.8321	8.3	(-36.0,44.4)
No	10	4	40.0	0.2	1698.8	20	7	35.0	0.9	816.9	0.8978	-5.0	(-43.3,30.8)

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.4945
<4	0.80	(0.18,3.64)	0.87	(0.36,2.57) (0.37,2.08)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					0.4395
=3	1.29	(0.34,5.19)	1.18	(0.51,4.16) (0.50,2.76)	
=4	0.33	(0.01,19.29)	0.43	(0.01,13.81) (0.04,4.82)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.6270
Yes	1.50	(0.21,13.98)	1.33	(0.33,8.42) (0.33,5.39)	
No	0.81	(0.16,4.28)	0.88	(0.32,3.33) (0.33,2.30)	

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.2.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	6	37.5			34	12	35.3				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	6	33.3			32	10	31.3				
Renal impairment at baseline												
Normal	16	6	37.5			26	9	34.6				
Mild	1	0	0.0			6	3	50.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	6	33.3	0.6	974.0	35	13	37.1	2.9	446.7	0.8862	3.8	(-25.4,30.0)
Sex													
Male	3	1	33.3	0.0	2282.8	14	5	35.7	1.5	329.1	1.0000	2.4	(-58.6,49.7)
Female	15	5	33.3	0.6	873.8	21	8	38.1	1.4	575.2	0.8933	4.8	(-28.4,35.8)
Age													
>= 50 years	4	1	25.0	0.1	1259.5	11	3	27.3	1.0	294.6	1.0000	2.3	(-55.5,46.5)
< 50 years	14	5	35.7	0.5	931.8	24	10	41.7	1.9	528.6	0.8013	6.0	(-27.6,36.6)
Race													
Asian	13	4	30.8	0.5	734.2	16	6	37.5	1.6	367.1	0.8076	6.7	(-30.0,42.4)
White	5	2	40.0	0.1	2809.6	19	7	36.8	1.3	548.7	1.0000	-3.2	(-52.2,39.4)
Region													
Europe + Africa + US	5	2	40.0	0.1	2809.6	21	7	33.3	1.5	458.2	1.0000	-6.7	(-54.5,34.9)
Asia(ex Japan) + Japan	13	4	30.8	0.5	734.2	14	6	42.9	1.4	434.0	0.6332	12.1	(-25.6,47.9)
BMI													
< 25 kg/m2	9	4	44.4			15	3	20.0					
25 to < 30 kg/m2	6	1	16.7			10	4	40.0					
>= 30 kg/m2	3	1	33.3			10	6	60.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.18	(0.35,4.15)	1.11	(0.52,3.13) (0.51,2.44)	
Sex					0.9487
Male	1.11	(0.07,39.00)	1.07	(0.25,27.89) (0.19,6.15)	
Female	1.23	(0.30,5.29)	1.14	(0.46,3.47) (0.46,2.81)	
Age					0.9507
>= 50 years	1.13	(0.08,39.00)	1.09	(0.16,28.32) (0.15,7.69)	
< 50 years	1.29	(0.32,5.39)	1.17	(0.49,3.66) (0.50,2.72)	
Race					0.7317
Asian	1.35	(0.27,7.01)	1.22	(0.41,4.47) (0.43,3.42)	
White	0.88	(0.11,8.95)	0.92	(0.30,8.69) (0.27,3.13)	
Region					0.5283
Europe + Africa + US	0.75	(0.09,7.64)	0.83	(0.27,7.87) (0.24,2.86)	
Asia(ex Japan) + Japan	1.69	(0.33,8.97)	1.39	(0.49,5.07) (0.50,3.84)	
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.2.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	3	60.0					
No	12	3	25.0			24	7	29.2					
Mutation status IL36RN after DNA resequencing													
Yes	6	3	50.0			8	3	37.5					
No	11	2	18.2			21	7	33.3					
Baseline GPPGA pustulation subscore													
<4	12	5	41.7	0.2	2467.9	22	9	40.9	1.9	468.9	1.0000	-0.8	(-35.9,33.2)
=4	6	1	16.7	0.4	241.9	13	4	30.8	1.0	403.6	0.8189	14.1	(-36.0,51.4)
Baseline GPPGA score													
=3	15	5	33.3	0.6	869.6	28	11	39.3	2.3	475.5	0.8304	6.0	(-26.4,34.8)
=4	3	1	33.3	0.0	2435.0	7	2	28.6	0.6	335.1	1.0000	-4.8	(-70.8,53.0)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	3	50.0					
No	15	6	40.0			29	10	34.5					
Background treatment prior to randomization													
Yes	8	2	25.0	0.2	880.1	15	5	33.3	1.0	524.8	0.8321	8.3	(-36.0,44.4)
No	10	4	40.0	0.4	1028.9	20	8	40.0	2.0	408.7		0.0	(-38.9,35.9)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					
Yes					
No					
Baseline GPPGA pustulation subscore					0.5625
<4	0.97	(0.22,4.34)	0.98	(0.42,3.03) (0.43,2.27)	
=4	2.22	(0.20,65.33)	1.85	(0.29,47.58) (0.26,13.19)	
Baseline GPPGA score					0.7724
=3	1.29	(0.34,5.19)	1.18	(0.51,4.16) (0.50,2.76)	
=4	0.80	(0.04,34.87)	0.86	(0.10,23.16) (0.12,6.23)	
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					0.7369
Yes	1.50	(0.21,13.98)	1.33	(0.33,8.42) (0.33,5.39)	
No	1.00	(0.20,5.21)	1.00	(0.39,4.44) (0.39,2.53)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	6	37.5			34	13	38.2				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	6	33.3			32	11	34.4				
Renal impairment at baseline												
Normal	16	6	37.5			26	10	38.5				
Mild	1	0	0.0			6	3	50.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	2	5.7	0.6	309.5	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	1	9.1					
< 50 years	14	1	7.1			24	1	4.2					
Race													
Asian	13	1	7.7			16	0	0.0					
White	5	0	0.0			19	2	10.5					
Region													
Europe + Africa + US	5	0	0.0			21	2	9.5					
Asia(ex Japan) + Japan	13	1	7.7			14	0	0.0					
BMI													
< 25 kg/m2	9	1	11.1			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	1	20.0				
No	12	1	8.3			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	1	12.5				
No	11	1	9.1			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	2	9.1				
=4	6	1	16.7			13	0	0.0				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	1	12.5			15	0	0.0				
No	10	0	0.0			20	2	10.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.2.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.2.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	2	5.7	1.9	108.1	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	1	9.1					
< 50 years	14	1	7.1			24	1	4.2					
Race													
Asian	13	1	7.7			16	0	0.0					
White	5	0	0.0			19	2	10.5					
Region													
Europe + Africa + US	5	0	0.0			21	2	9.5					
Asia(ex Japan) + Japan	13	1	7.7			14	0	0.0					
BMI													
< 25 kg/m2	9	1	11.1			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	1	20.0				
No	12	1	8.3			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	1	12.5				
No	11	1	9.1			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	2	9.1				
=4	6	1	16.7			13	0	0.0				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	1	12.5			15	0	0.0				
No	10	0	0.0			20	2	10.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	131.9	35	2	5.7	4.8	41.9	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	1	9.1					
< 50 years	14	1	7.1			24	1	4.2					
Race													
Asian	13	1	7.7			16	0	0.0					
White	5	0	0.0			19	2	10.5					
Region													
Europe + Africa + US	5	0	0.0			21	2	9.5					
Asia(ex Japan) + Japan	13	1	7.7			14	0	0.0					
BMI													
< 25 kg/m2	9	1	11.1			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	1	10.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	1	20.0				
No	12	1	8.3			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	1	12.5				
No	11	1	9.1			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	2	9.1				
=4	6	1	16.7			13	0	0.0				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	1	12.5			15	0	0.0				
No	10	0	0.0			20	2	10.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.2.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Overall	18	0	0.0			35	0	0.0				
Sex												
Male	3	0	0.0			14	0	0.0				
Female	15	0	0.0			21	0	0.0				
Age												
>= 50 years	4	0	0.0			11	0	0.0				
< 50 years	14	0	0.0			24	0	0.0				
Race												
Asian	13	0	0.0			16	0	0.0				
White	5	0	0.0			19	0	0.0				
Region												
Europe + Africa + US	5	0	0.0			21	0	0.0				
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0				
BMI												
< 25 kg/m2	9	0	0.0			15	0	0.0				
25 to < 30 kg/m2	6	0	0.0			10	0	0.0				
>= 30 kg/m2	3	0	0.0			10	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall				
Sex				
Male				
Female				
Age				
>= 50 years				
< 50 years				
Race				
Asian				
White				
Region				
Europe + Africa + US				
Asia(ex Japan) + Japan				
BMI				
< 25 kg/m2				
25 to < 30 kg/m2				
>= 30 kg/m2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	0	0.0				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	0	0.0				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	0	0.0				
Baseline GPPGA score												
=3	15	0	0.0			28	0	0.0				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	0	0.0				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.2.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	0	0.0				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	0	0.0				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 1 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	0	0.0			35	0	0.0				
Sex												
Male	3	0	0.0			14	0	0.0				
Female	15	0	0.0			21	0	0.0				
Age												
>= 50 years	4	0	0.0			11	0	0.0				
< 50 years	14	0	0.0			24	0	0.0				
Race												
Asian	13	0	0.0			16	0	0.0				
White	5	0	0.0			19	0	0.0				
Region												
Europe + Africa + US	5	0	0.0			21	0	0.0				
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0				
BMI												
< 25 kg/m2	9	0	0.0			15	0	0.0				
25 to < 30 kg/m2	6	0	0.0			10	0	0.0				
>= 30 kg/m2	3	0	0.0			10	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall				
Sex				
Male				
Female				
Age				
>= 50 years				
< 50 years				
Race				
Asian				
White				
Region				
Europe + Africa + US				
Asia(ex Japan) + Japan				
BMI				
< 25 kg/m2				
25 to < 30 kg/m2				
>= 30 kg/m2				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	0	0.0				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	0	0.0				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	0	0.0				
Baseline GPPGA score												
=3	15	0	0.0			28	0	0.0				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	0	0.0				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	0	0.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	0	0.0				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	0	0.0				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 4 - SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	5.0	19.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	0	0.0					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	0	0.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.2.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity excluding disease-specific adverse events overall and by subgroup up to week 12- SAF (OC)

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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1.1.3 Adverse events of special interest

Table 1.3.1 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.1 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.1 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.1 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.1 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.1 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.2 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.2 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.3.2 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Table 1.3.2 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.2 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.2 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.3 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 12 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.3 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 12 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.3 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 12 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.3 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 12 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.3 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 12 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.3 Proportion and incidence rate of patients with adverse events of special interest by category overall and by subgroup up to week 12 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.4 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.4 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.4 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.4 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.4 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.4 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.5 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.5 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.5 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.5 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.5 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.5 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.6 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.6 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.6 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.6 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.6 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.6 Proportion and incidence rate of patients with adverse events of special interest by category serious adverse events overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.7 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.8 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.9 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.10 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.10 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.10 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.10 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.10 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.10 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.11 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.3.11 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.3.11 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.3.11 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.3.11 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.3.12 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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AE of special interest: HEPATIC INJURIES

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Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.3.12 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.12 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.12 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
AE of special interest: HEPATIC INJURIES

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

AEs of special interest are only displayed if at least one event occurred

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.3.13 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.14 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.15 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with severe maximum intensity overall and by subgroup up to week 12- SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.16 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.17 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.3.18 Proportion and incidence rate of patients with adverse events of special interest by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)

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1.1.4 User defined adverse events concepts

Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	2	5.7	0.6	313.5	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	289.9	35	3	8.6	0.6	478.5	0.8564	3.0	(-19.5,19.0)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	2	9.5					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	3	12.5					
Race													
Asian	13	1	7.7			16	3	18.8					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	3	21.4					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	3	30.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	1	6.7			28	3	10.7				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	3	10.3				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	3	15.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	3	8.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	2	7.7				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	289.9	35	3	8.6	0.6	478.5	0.8564	3.0	(-19.5,19.0)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	2	9.5					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	3	12.5					
Race													
Asian	13	1	7.7			16	3	18.8					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	3	21.4					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	3	30.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	1	6.7			28	3	10.7				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	3	10.3				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	3	15.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	3	8.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	2	7.7				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.1 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.9	107.6	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	213.6	35	3	8.6	1.8	167.8	0.8564	3.0	(-19.5,19.0)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	2	9.5					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	3	12.5					
Race													
Asian	13	1	7.7			16	3	18.8					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	3	21.4					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	3	30.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	1	6.7			28	3	10.7				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	3	10.3				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	3	15.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	3	8.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	2	7.7				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	213.6	35	3	8.6	1.8	167.8	0.8564	3.0	(-19.5,19.0)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	2	9.5					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	3	12.5					
Race													
Asian	13	1	7.7			16	3	18.8					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	3	21.4					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	3	30.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	1	6.7			28	3	10.7				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	3	10.3				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	3	15.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	3	8.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	2	7.7				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.2 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	126.4	35	2	5.7	4.8	41.9	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	1	7.7			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	2	10.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	151.6	35	4	11.4	4.6	87.9	0.7740	5.9	(-17.0,22.7)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	3	14.3					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	4	16.7					
Race													
Asian	13	1	7.7			16	3	18.8					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	1	7.7			14	3	21.4					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	1	16.7			10	3	30.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	3	23.1				
Baseline GPPGA score												
=3	15	1	6.7			28	4	14.3				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	4	13.8				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	4	20.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	4	11.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	3	9.4				
Renal impairment at baseline												
Normal	16	1	6.3			26	3	11.5				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	151.6	35	4	11.4	4.6	87.9	0.7740	5.9	(-17.0,22.7)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	3	14.3					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	4	16.7					
Race													
Asian	13	1	7.7			16	3	18.8					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	1	7.7			14	3	21.4					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	1	16.7			10	3	30.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	3	12.5				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	3	14.3				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	3	23.1				
Baseline GPPGA score												
=3	15	1	6.7			28	4	14.3				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	4	13.8				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
No	10	1	10.0			20	4	20.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	4	11.8				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	3	9.4				
Renal impairment at baseline												
Normal	16	1	6.3			26	3	11.5				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.3 Proportion and incidence rate of patients with user defined adverse events concepts by category overall and by subgroup up to week 12 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.4 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.5 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.8	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	2	9.5					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	2	7.7				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.8	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	2	9.5					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	2	8.3				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	2	9.5				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	2	15.4				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	2	7.7				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.6 Proportion and incidence rate of patients with user defined adverse events concepts by category serious adverse events overall and by subgroup week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	2	5.7	0.6	313.5	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	289.9	35	2	5.7	0.6	313.5	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	1	7.7			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
No	10	1	10.0			20	2	10.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	289.9	35	2	5.7	0.6	313.5	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	1	7.7			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
No	10	1	10.0			20	2	10.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.7 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.9	107.6	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	213.6	35	2	5.7	1.9	107.6	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	1	7.7			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
No	10	1	10.0			20	2	10.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	213.6	35	2	5.7	1.9	107.6	1.0000	0.2	(-21.9,15.4)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	1	7.7			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
No	10	1	10.0			20	2	10.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	2	6.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.8 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.9	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.9	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.9	0.4283	5.7	(-13.7,19.5)
Sex													
Male	3	0	0.0			14	1	7.1					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	2	8.3					
Race													
Asian	13	0	0.0			16	2	12.5					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	2	14.3					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	2	20.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	1	4.5				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	2	7.1				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	2	6.9				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	2	10.0				

User-defined AE categories are only displayed if at least one event occurred within that category

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	2	5.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	2	6.3				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	1	16.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.9 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with mild maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup / Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

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User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	1	2.9	0.6	154.1	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.10 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 1 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup / Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)		Risk ratio	Risk (exact 95% CI) (asymp 95% CI)		p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)		
Sex						
Male						
Female						
Age						
>= 50 years						
< 50 years						
Race						
Asian						
White						
Region						
Europe + Africa + US						
Asia(ex Japan) + Japan						
BMI						
< 25 kg/m2						
25 to < 30 kg/m2						
>= 30 kg/m2						

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup / Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	1	2.9	1.9	53.5	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.11 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 4 - SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	126.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	1	6.7			21	0	0.0					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	0	0.0					
Race													
Asian	13	1	7.7			16	0	0.0					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	0	0.0					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	0	0.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	0	0.0				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	0	0.0				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	0	0.0				
=4	6	0	0.0			13	0	0.0				
Baseline GPPGA score												
=3	15	1	6.7			28	0	0.0				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	0	0.0				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	1	10.0			20	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	0	0.0				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	0	0.0				
Renal impairment at baseline												
Normal	16	1	6.3			26	0	0.0				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Angioedema

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	126.4	35	1	2.9	4.8	20.9	0.7741	-2.7	(-24.4,11.7)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	1	7.7			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
No	10	1	10.0			20	1	5.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	0	0.0				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	126.4	35	1	2.9	4.8	20.9	0.7741	-2.7	(-24.4,11.7)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	1	6.7			21	1	4.8					
Age													
>= 50 years	4	1	25.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	1	7.7			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	1	7.7			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	1	16.7			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	1	16.7			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	1	8.3			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	1	6.7			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	1	6.7			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
No	10	1	10.0			20	1	5.0				
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	0	0.0				
Renal impairment at baseline												
Normal	16	1	6.3			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk ratio (exact 95% CI) (asymp 95% CI)	p-value**
No				
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Infections 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	4.8	20.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	1	6.3					
White	5	0	0.0			19	0	0.0					
Region													
Europe + Africa + US	5	0	0.0			21	0	0.0					
Asia(ex Japan) + Japan	13	0	0.0			14	1	7.1					
BMI													
< 25 kg/m2	9	0	0.0			15	0	0.0					
25 to < 30 kg/m2	6	0	0.0			10	1	10.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	0	0.0				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.12 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with moderate maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Serious infections

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.13 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with severe maximum intensity overall and by subgroup up to week 1 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.4.14 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with severe maximum intensity overall and by subgroup up to week 4 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.4.15 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with severe maximum intensity overall and by subgroup up to week 12- SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.4.16 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 1 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.4.17 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 4 - SAF (OC)

---------- No data satisfied to be displayed ----------

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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	5.0	19.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	0	0.0					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	0	0.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)		Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

User-defined AE categories are only displayed if at least one event occurred within that category

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Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
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Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	1	2.9	5.0	19.9	0.7606	2.9	(-16.4,15.5)
Sex													
Male	3	0	0.0			14	0	0.0					
Female	15	0	0.0			21	1	4.8					
Age													
>= 50 years	4	0	0.0			11	0	0.0					
< 50 years	14	0	0.0			24	1	4.2					
Race													
Asian	13	0	0.0			16	0	0.0					
White	5	0	0.0			19	1	5.3					
Region													
Europe + Africa + US	5	0	0.0			21	1	4.8					
Asia(ex Japan) + Japan	13	0	0.0			14	0	0.0					
BMI													
< 25 kg/m2	9	0	0.0			15	1	6.7					
25 to < 30 kg/m2	6	0	0.0			10	0	0.0					
>= 30 kg/m2	3	0	0.0			10	0	0.0					

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N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
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User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)		Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.06, inf)	inf	(0.04, inf)	
Sex					
Male					
Female					
Age					
>= 50 years					
< 50 years					
Race					
Asian					
White					
Region					
Europe + Africa + US					
Asia(ex Japan) + Japan					
BMI					
< 25 kg/m2					
25 to < 30 kg/m2					
>= 30 kg/m2					

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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
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Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Mutation status IL36RN												
Yes	2	0	0.0			5	0	0.0				
No	12	0	0.0			24	1	4.2				
Mutation status IL36RN after DNA resequencing												
Yes	6	0	0.0			8	0	0.0				
No	11	0	0.0			21	1	4.8				
Baseline GPPGA pustulation subscore												
<4	12	0	0.0			22	0	0.0				
=4	6	0	0.0			13	1	7.7				
Baseline GPPGA score												
=3	15	0	0.0			28	1	3.6				
=4	3	0	0.0			7	0	0.0				
Baseline plaque psoriasis												
Yes	3	0	0.0			6	0	0.0				
No	15	0	0.0			29	1	3.4				
Background treatment prior to randomization												
Yes	8	0	0.0			15	0	0.0				
No	10	0	0.0			20	1	5.0				

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Subgroup / Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				
Yes				
No				
Baseline GPPGA pustulation subscore				
<4				
=4				
Baseline GPPGA score				
=3				
=4				
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				
Yes				
No				

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*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	0	0.0			34	1	2.9				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	0	0.0			32	1	3.1				
Renal impairment at baseline												
Normal	16	0	0.0			26	1	3.8				
Mild	1	0	0.0			6	0	0.0				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
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Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
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Table 1.4.18 Proportion and incidence rate of patients with user defined adverse events concepts by category adverse events with life-threatening maximum intensity overall and by subgroup up to week 12- SAF (OC)
User-defined AE Category: Hypersensitivity 'ALL'

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	Risk (exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

User-defined AE categories are only displayed if at least one event occurred within that category

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
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End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute encephalitis with refractory, repetitive partial seizures
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute motor axonal neuropathy
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute motor-sensory axonal neuropathy
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Air-borne transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis reactive
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthropod-borne disease
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Axonal and demyelinating polyneuropathy
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial disease carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bickerstaff's encephalitis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bullous oedema of the bladder
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic gastritis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic hepatitis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ciliary ganglionitis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Community acquired infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous malacoplakia
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Degenerative multivalvular disease
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diphtheria carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Direct infection transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis post immunisation
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis post varicella
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis rheumatic
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erythema marginatum
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Faecal-oral transmission of infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Febrile infection-related epilepsy syndrome
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Follicular cystitis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Food poisoning
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal disease carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Granulomatous lymphadenitis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Guillain-Barre syndrome
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HTLV-1 carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis chronic active
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis chronic persistent
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis fulminant
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human immunodeficiency virus transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Iatrogenic infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Indirect infection transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infantile acropustulosis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection transmission via personal contact
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection via vaccinee
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infectious disease carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kawasaki's disease

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratoderma blenorrhagica
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malacoplakia
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malacoplakia gastrointestinal
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malacoplakia of bone
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malacoplakia vesicae
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Multisystem inflammatory syndrome in children
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterial disease carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis post infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nosocomial infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis rheumatic
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Poncet's disease
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post herpetic neuralgia
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post infection glomerulonephritis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post polio syndrome
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post streptococcal glomerulonephritis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Primary transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Progressive massive fibrosis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Psorospermiasis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Reye's syndrome
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rheumatic fever
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rheumatic heart disease
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Roseola
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	SARS-CoV-2 carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	SJS-TEN overlap
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scleroedema
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Secondary amyloidosis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Secondary transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sexual transmission of infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sexually transmitted disease
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sexually transmitted disease carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sporadic infantile bilateral striatal necrosis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stevens-Johnson syndrome
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subacute inflammatory demyelinating polyneuropathy
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subacute sclerosing panencephalitis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Suspected transmission of an infectious agent via product
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sydenham's chorea
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thyroiditis subacute
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tick paralysis
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Toxic epidermal necrolysis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Transmission of an infectious agent via product
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Transmission of an infectious agent via transplant
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Typhoid carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccine bacteria shedding
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccine virus shedding
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vector-borne transmission of infection
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vertical infection transmission
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral disease carrier
Infections 'ALL'	Ancillary infectious topics (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral hepatitis carrier
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Achromobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acid fast bacilli infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acinetobacter bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acinetobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acinetobacter sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acrodermatitis chronica atrophicans
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Actinomycosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Actinomycotic abdominal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Actinomycotic pulmonary infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Actinomycotic sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Actinomycotic skin infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenopathy syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Administration site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aerococcus urinae infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aeromonas infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alcaligenes infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alopecia syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alpha haemolytic streptococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Angina gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anicteric leptospirosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anorectal cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anorectal infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anthrax
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anthrax sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Antibiotic associated colitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aortic aneurysm syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aortitis salmonella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aortitis syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Application site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arteriosclerotic gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis salmonella

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Asymptomatic bacteriuria
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacillary angiomatosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacillus bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacillus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterascites
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial abdominal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial abscess central nervous system
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial allergy
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial blepharitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial colitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial dacryocystitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial diarrhoea
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial endophthalmitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial food poisoning
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial gingivitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial iritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial labyrinthitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial myositis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial parotitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial pericarditis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial prostatitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial pyelonephritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial rhinitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial salpingitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial tracheitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial ureteritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial urethritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial vaginosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial vulvovaginitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacteriuria
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacteriuria in pregnancy
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacteroides infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bartonellosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Beta haemolytic streptococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bifidobacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary tract infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bordetella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Borrelia infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Botryomycosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Botulism
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brachyspira infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brazilian purpuric fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Breast cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brevibacterium infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis moraxella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis pneumococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brucella sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brucellosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bubonic plague
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bullous erysipelas
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bullous impetigo
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burkholderia cepacia complex infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burkholderia cepacia complex sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burkholderia gladioli infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burkholderia infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burkholderia mallei infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burkholderia pseudomallei infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bursitis infective staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Campylobacter colitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Campylobacter gastroenteritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Campylobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Campylobacter sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Campylobacter urinary tract infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Capnocytophaga infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Capnocytophaga sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cardiovascular syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cat scratch disease
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Catheter site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis enterococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis of male external genital organ
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis orbital
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis pasteurella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral aneurysm ruptured syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervicitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervicitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chancroid
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cholera
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Citrobacter bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Citrobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Citrobacter sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clostridial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clostridial sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clostridium bacteraemia

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clostridium colitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clostridium difficile colitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clostridium difficile infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Colon gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Condyloma latum
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital syphilitic encephalitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital syphilitic meningitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital syphilitic osteochondritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis gonococcal neonatal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Corynebacterium bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Corynebacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Corynebacterium sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cronobacter bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cronobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cronobacter necrotising enterocolitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous anthrax
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous listeriosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous nocardiosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis escherichia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis klebsiella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis pseudomonal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Delftia acidovorans infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diabetic gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diaphragmatic hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diphtheria
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear infection staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eczema impetiginous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Empedobacter brevis infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis meningococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endemic syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis enterococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis meningococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis pseudomonal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endometritis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endometritis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enteritis necroticans

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterobacter bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterobacter pneumonia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterobacter sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterobacter tracheobronchitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterococcal bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterococcal gastroenteritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterococcal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterocolitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epididymo-orchitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epiglottitis haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erysipelas
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erysipelothrix infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erysipelothrix sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erythema migrans
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erythrasma
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia peritonitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia pyelonephritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia urinary tract infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Escherichia vaginitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eubacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	External ear cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Femoral hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Flavobacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Folliculitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Furuncle
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fusobacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gangrene neonatal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gangrenous balanitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gardnerella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gas gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastric ulcer helicobacter
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastritis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis Escherichia coli
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis aerobacter
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis aeromonas
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis bacillus

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis clostridial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis listeria
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis paracolon bacillus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis proteus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis pseudomonas
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis salmonella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis shigella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis vibrio
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis yersinia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal anthrax
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal bacterial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal bacterial overgrowth
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genitourinary tract gonococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Giant fornix syndrome
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gonococcal heart disease
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gonococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gonococcal pelvic inflammatory disease
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gonorrhoea
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Granulicatella bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Granulicatella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Granuloma inguinale
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Group B streptococcus neonatal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemophilus bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemophilus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemophilus sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Helicobacter duodenal ulcer
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Helicobacter duodenitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Helicobacter gastritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Helicobacter infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Helicobacter sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic gas gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ileal gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Implant site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Incision site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Incisional hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infusion site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Inguinal hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Injection site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intestinal gangrene

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Janeway lesion
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Jejunal gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratosis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Klebsiella bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Klebsiella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Klebsiella sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lacrimal sac cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lactobacillus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Latent syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Legionella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lemierre syndrome
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Leptospira sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Leptospirosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Leptotrichia infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Leuconostoc infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lineal gingival erythema
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Listeraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Listeria encephalitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Listeria sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Listeriosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lower respiratory tract infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lyme carditis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lyme disease
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphadenitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malignant syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Medical device site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis Escherichia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis borrelia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis cronobacter
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis enterococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis leptospiral
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis listeria
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis meningococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis pneumococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis salmonella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningococcal bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningococcal carditis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningococcal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningoencephalitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Methylobacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Micrococcal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Micrococcus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Moraxella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Morganella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis meningococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nail bed infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrobacillosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising fasciitis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising fasciitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising ulcerative gingivostomatitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising ulcerative periodontitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neisseria infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nephritis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neuroborreliosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neurosyphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nocardia sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nocardiosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oesophagitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Optic neuritis meningococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral bacterial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oropharyngeal gonococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osler's nodes
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis salmonella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis externa bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media moraxella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media pneumococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ovarian bacterial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Overgrowth bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreatitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pantoea agglomerans infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paratyphoid fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paronychia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parvimonas infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parvimonas micra infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pasteurella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Penile gangrene

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peptic ulcer helicobacter
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peptostreptococcus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perianal streptococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis meningococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perichondritis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perihepatitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periorbital cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periporitis staphylogenes
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis pneumococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis syphilitic
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pertussis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peruvian wart
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pinta
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plague
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plague sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pleural infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumococcal bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumococcal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia acinetobacter
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia anthrax
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia bordetella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia escherichia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia klebsiella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia legionella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia moraxella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia pneumococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia proteus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia pseudomonal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia salmonella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia serratia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia tularaemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonic plague
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pontiac fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Porphyromonas infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post procedural cellulitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post treatment Lyme disease syndrome
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Primary syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Propionibacterium infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prostatitis Escherichia coli
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prostatitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proteus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Providencia infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Providencia urinary tract infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomembranous colitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonal bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonal skin infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonas aeruginosa meningitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonas bronchitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonas infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudomonas peritonitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary nocardiosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Puncture site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Purple urine bag syndrome
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyoderma streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyomyositis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Raoultella ornithinolytica infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Relapsing fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Renal syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory tract infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinoscleroma
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhodococcus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salmonella bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salmonella sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salmonellosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salpingitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scarlet fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scrotal gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Secondary syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Seminal vesiculitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sepsis pasteurella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic arthritis haemophilus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic arthritis neisserial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic arthritis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic arthritis streptobacillus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic arthritis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Serratia bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Serratia infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Serratia sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Severe invasive streptococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Shewanella algae bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Shigella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Shigella sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sinusitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Skin bacterial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Small intestine gangrene
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sphingomonas paucimobilis bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sphingomonas paucimobilis infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spirillary fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spirochaetal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal abscess
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal blepharitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal impetigo
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal mediastinitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal osteomyelitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal parotitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal pharyngitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal scalded skin syndrome
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal skin infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Staphylococcal toxaemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stenotrophomonas bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stenotrophomonas infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stenotrophomonas sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stoma site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stomatococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptobacillary fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptobacillus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal abscess
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal bronchitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal endocarditis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal impetigo
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Streptococcal urinary tract infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Superinfection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sycosis barbae
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Syphilis anal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Syphilis genital

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Syphilis musculoskeletal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Syphilitic endocarditis of heart valve
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Systemic bacterial infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Systemic bartonellosis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tertiary syphilis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tetanus
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tetanus neonatorum
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tonsillitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tonsillitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Toxic shock syndrome staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Toxic shock syndrome streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheobronchitis bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trench fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculous abscess central nervous system
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tularaemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Typhoid fever
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Umbilical hernia gangrenous
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Upper respiratory tract infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethritis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection enterococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection pseudomonal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urogenital infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccination site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaginal cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaginitis gardnerella
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Veillonella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vessel puncture site cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vibrio vulnificus infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulval cellulitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis gonococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis streptococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Waterhouse-Friderichsen syndrome
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Weil's disease
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Weissella infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Whipple's disease
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection bacterial
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection pseudomonas
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection staphylococcal
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yaws
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yaws of bone
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yaws of skin

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yersinia bacteraemia
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yersinia infection
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yersinia meningitis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yersinia sepsis
Infections 'ALL'	Bacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zoonotic bacterial infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal chlamydia infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chlamydial cervicitis
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chlamydial infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chlamydial pelvic inflammatory disease
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis chlamydial
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection chlamydial
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genitourinary chlamydia infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gynaecological chlamydia infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Inclusion conjunctivitis
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Inclusion conjunctivitis neonatal
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphogranuloma venereum
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritoneal chlamydia infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngeal chlamydia infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia chlamydial
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis chlamydial
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Psittacosis
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory tract chlamydial infection
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trachoma
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethritis chlamydial
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaginitis chlamydial
Infections 'ALL'	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis chlamydial
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acariasis
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acarodermatitis
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthropod infestation
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bed bug infestation
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Demodicidosis
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Flea infestation
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hirudiniasis
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infestation
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lice infestation
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myiasis
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trombidiasis
Infections 'ALL'	Ectoparasitic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tungiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute pulmonary histoplasmosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Allergic bronchopulmonary mycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Allescheriosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alternaria infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal tinea

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aspergilloma
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aspergillosis oral
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aspergillus infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Aureobasidium pullulans infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Balanitis candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary tract infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Black piedra
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bladder candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Blastomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Body tinea
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchopulmonary aspergillosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchopulmonary aspergillosis allergic
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida cervicitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida endophthalmitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida nappy rash
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida osteomyelitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida pneumonia
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida retinitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida sepsis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candida urethritis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Candidiasis of trachea
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Central nervous system fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral aspergillosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chromoblastomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic pulmonary histoplasmosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coccidioides encephalitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coccidioidomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cryptococcal cutaneous infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cryptococcal fungaemia
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cryptococcal meningoencephalitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cryptococcosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous blastomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous coccidioidomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous mucormycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous sporotrichosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Denture stomatitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dermatophytosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dermatophytosis of nail
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated aspergillosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated blastomycosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated coccidioidomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated cryptococcosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated mucormycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated paracoccidioidomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated sporotrichosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated trichosporonosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis histoplasma
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterocolitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epididymitis blastomyces
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Exserohilum infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal abscess central nervous system
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal balanitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal cystitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal endocarditis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal labyrinthitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal oesophagitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal paronychia
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal peritonitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal pharyngitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal retinitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal rhinitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal sepsis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal skin infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal tracheitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungal urethritis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Funguria
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fusarium infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastritis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis cryptococcal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal mucormycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Geotrichum infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatosplenic candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Histoplasmosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Histoplasmosis cutaneous
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Histoplasmosis disseminated

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kerion
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngeal cryptococcosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lobomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lower respiratory tract infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphadenitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malassezia infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis aspergillus
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis coccidioides
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis cryptococcal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis exserohilum
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis histoplasma
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Microsporum infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mucocutaneous candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mucormycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycetoma mycotic
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycotic corneal ulcer
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycotic endophthalmitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycotoxicosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis mycotic
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nail candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nasal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising fasciitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neonatal candida infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neoscytalidium infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neurocryptococcosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oesophageal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Onychomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oro-pharyngeal aspergillosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oropharyngeal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oropharyngitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osseous cryptococcosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis blastomyces
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis externa candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis externa fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Overgrowth fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreatitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paracoccidioides infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Penicillium infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis histoplasma
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritoneal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Phaeohyphomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Phaeohyphomycotic brain abscess
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumocystis jirovecii infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumocystis jirovecii pneumonia
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia blastomyces
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia cryptococcal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Presumed ocular histoplasmosis syndrome
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis monilial
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudallescheria infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudallescheria sepsis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary mucormycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary paracoccidioidomycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary sporotrichosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary trichosporonosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelonephritis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pythium insidiosum infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory moniliasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory tract infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retinitis histoplasma
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinocerebral mucormycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinosporidiosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scedosporium infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scopulariopsis infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Severe asthma with fungal sensitisation
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sinusitis aspergillus
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sinusitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Skin candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sporotrichosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stoma site candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Superinfection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Systemic candida
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Systemic mycosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea barbae
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea blanca
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea capitis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea cruris
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea faciei
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea imbricata

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea manuum
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea nigra
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea pedis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tinea versicolour
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tongue fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tonsillitis fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Torulopsis infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichophytic granuloma
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichophytosis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichosporon infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Upper respiratory fungal infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urogenital infection fungal
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginal candidiasis
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginal mycotic infection
Infections 'ALL'	Fungal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection fungal
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Angiostrongylus infection
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anisakiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ascariasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary tract infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Capillariasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cestode infection
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clonorchiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous larva migrans
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dicrocoeliasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diphyllobothriasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dipylidiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dirofilariasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated strongyloidiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dracunculiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Echinococciasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterobiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterocolitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fascioliasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fasciolopsiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Filariasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Filariasis lymphatic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastritis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gnathostomiasis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Helminthic infection
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic echinococciasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Heterophyiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hookworm infection
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hymenolepiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphadenitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningoencephalitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Metagonimiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nematodiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neurocysticercosis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Onchocerciasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Onchodermatitis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Opisthorchiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral helminthic infection
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreatitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paragonimiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary echinococciasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Renal echinococciasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Schistosomiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Schistosomiasis bladder
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Schistosomiasis cutaneous
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Schistosomiasis liver
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Skin infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Strongyloidiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Syngamiasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Taeniasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thyroid echinococciasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Toxocariasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trematode infection
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichiniasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichostrongyliasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichuriasis
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tropical eosinophilia
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Upper respiratory tract infection helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis helminthic
Infections 'ALL'	Helminthic disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection helminthic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal hernia infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal wall abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abdominal wall infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abortion infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess intestinal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess jaw
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess limb
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess neck
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess of external auditory meatus
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess of eyelid
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess of salivary gland
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess oral
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess rupture
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess soft tissue
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Abscess sweat gland
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acne pustular
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Activated PI3 kinase delta syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute endocarditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute sinusitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoiditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Administration site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Administration site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Administration site joint infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Administration site pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adrenal gland abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adrenalitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alveolar osteitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amniotic cavity infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amniotic infection syndrome of Blane
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal fistula infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anal papillitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anastomotic infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anorectal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Appendiceal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Appendicitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Appendicitis perforated
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Application site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Application site folliculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Application site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Application site joint infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Application site pustules
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arteriovenous fistula site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arteriovenous graft site abscess

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arteriovenous graft site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arteritis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Atypical pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacteraemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial toxaemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacterial translocation
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bacteroides bacteraemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Balanoposthitis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bartholin's abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bartholinitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bezold abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biloma infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bladder diverticulitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Blebitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Blister infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bone abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brain abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Brain empyema
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Breast abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Breast discharge infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Burn infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bursitis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	CNS ventriculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Carbuncle
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cardiac infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cardiac valve abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cardiac valve vegetation
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Catheter site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Catheter site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Catheter site pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cavernous sinus thrombosis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis laryngeal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cellulitis pharyngeal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Central nervous system abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Central nervous system infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral septic infarct
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervicitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chest wall abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cholangitis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cholecystitis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chorioretinitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic sinusitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic tonsillitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Clitoris abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coinfection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Colonic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Colostomy infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Complicated appendicitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Corneal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Corneal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cranial nerve infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cross infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Croup infectious
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dacryocanaliculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dacryocystitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dental fistula
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dental gangrene
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dermatitis infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dermo-hypodermitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Device related bacteraemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Device related infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Device related sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diabetic foot infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diarrhoea infectious
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diarrhoea infectious neonatal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diverticulitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diverticulitis intestinal haemorrhagic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Diverticulitis intestinal perforated
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Douglas' abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dural abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dysentery
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear lobe infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ecthyma
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eczema infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Embolic pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Emphysematous cholecystitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Emphysematous cystitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Emphysematous pyelonephritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Empyema
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis brain stem
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis lethargica

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalomyelitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endometritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endometritis decidual
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endophthalmitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endotoxaemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endotoxic shock
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enteritis infectious
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterocolitis infectious
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ependymitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epididymitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epiglottitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epiglottitis obstructive
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erysipeloid
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Extradural abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection intraocular
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eyelid boil
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eyelid folliculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eyelid infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fallopian tube abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fascial infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Febrile infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Focal peritonitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fournier's gangrene
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fracture infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fungaemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Funisitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gallbladder abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gallbladder empyema
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastric infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection female
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection male
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital ulcer syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genitourinary tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gingival abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gingivitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gradenigo's syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Graft infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Groin abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Groin infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haematoma infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemorrhagic pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemorrhoid infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic cyst infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis post transfusion
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatobiliary infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatosplenic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hordeolum
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hydrocele male infected
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hypopyon
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Impetigo
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Implant site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Implant site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Implant site pustules
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Incision site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Induced abortion infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infantile septic granulomatosis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected bite
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected bunion
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected cyst
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected dermal cyst
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected fistula
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected gouty tophus
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected large intestinal ulcer
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected lymphocele
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected naevus
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected neoplasm
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected seroma
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected skin ulcer
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected urinoma
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected varicose vein
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infected vasculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection in an immunocompromised host
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection masked
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection parasitic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection reactivation
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection susceptibility increased
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infectious crystalline keratopathy
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infectious iridocyclitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infectious pleural effusion
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infectious thyroiditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective aneurysm
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective aortitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective chondritis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective corneal ulcer
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective episcleritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective exacerbation of bronchiectasis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective exacerbation of chronic obstructive airways disease
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective glossitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective iritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective keratitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective mesenteric panniculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective myositis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective pericardial effusion
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective periostitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective pulmonary exacerbation of cystic fibrosis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective scleritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective spondylitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective tenosynovitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective thrombosis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infective uveitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infusion site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infusion site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infusion site joint infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infusion site pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Injection site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Injection site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Injection site joint infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Injection site pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Instillation site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Instillation site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Instillation site pustules
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intervertebral discitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intestinal fistula infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intestinal sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intracranial infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intrauterine infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Joint abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratouveitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kidney infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Labyrinthitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lacrimal gland abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Large intestine infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngopharyngitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngotracheitis obstructive
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lip infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Liver abscess

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Localised infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lochial infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lower respiratory tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ludwig angina
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lung abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymph gland infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymph node abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphangitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastitis postpartum
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastoid abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastoid empyema
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mastoiditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mediastinal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mediastinitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Medical device site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Medical device site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Medical device site joint infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Medical device site pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis aseptic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis neonatal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mesenteric abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Miliary pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mononucleosis syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mucosal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Muscle abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myelitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocardiac abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis infectious
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis septic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myometritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myringitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nail bed infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nail infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nasal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nasal vestibulitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nasopharyngitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising fasciitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising soft tissue infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neonatal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neonatal infective mastitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neonatal pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neovaginal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neurological infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neutropenic infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neutropenic sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nipple infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Obstetric infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oculoglandular syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oesophageal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oesophageal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Omphalitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oophoritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ophthalmia neonatorum
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Opportunistic infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Orbital infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Orchitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis acute
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis chronic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis externa
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media acute
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media chronic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otosalpingitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ovarian abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Overgrowth of nonsusceptible organisms
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreas infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreatic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Panencephalitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Papillon-Lefevre syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paracancerous pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parametric abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parametritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paranasal mucopyocoele
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paranasal sinus abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parapharyngeal space infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parasite allergy
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parasitic encephalitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parasitic gastroenteritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parasitic oesophagitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parasitic pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paraspinal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parathyroid gland abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parotid abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parotitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pathogen resistance
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pelvic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pelvic infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pelvic inflammatory disease
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pelvic sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Penile abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Penile infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peri-implantitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericoronitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perihepatic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perihepatitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perineal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perineal cellulitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perineal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perinephric abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periodontal destruction
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periodontitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periorbital abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periorbital infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peripheral nerve infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perirectal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritoneal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonsillar abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonsillitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Periumbilical abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Petrositis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngeal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngeal pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngolaryngeal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngotonsillitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Phlebitis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pilonidal cyst
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pilonidal cyst congenital
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pitted keratolysis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pleural infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia necrotising
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Portal pyaemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post abortion infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post procedural infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post procedural pneumonia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post procedural sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Postoperative abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Postoperative wound infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Postpartum sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prostate infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prostatic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pseudoaneurysm infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Psoas abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Puerperal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Puerperal pyrexia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulpitis dental
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Puncture site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Puncture site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Purulence
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Purulent discharge
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Purulent pericarditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Purulent synovitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pustule
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelocystitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelonephritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelonephritis acute
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelonephritis chronic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyloric abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyoderma
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyometra
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyonephrosis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyopneumothorax
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyospermia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyuria
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rash pustular
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rectal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rectovaginal septum abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Recurrent pyogenic cholangitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Recurrent subareolar breast abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Renal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Renal cyst infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Renal graft infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retinitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retroperitoneal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retroperitoneal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retroperitonitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinolaryngitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinotracheitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Root canal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salpingitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salpingo-oophoritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scrotal abscess

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scrotal cellulitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scrotal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sebaceous gland infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Seminal vesicle abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Seminal vesicular infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sepsis neonatal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sepsis syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic coagulopathy
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic embolus
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic encephalopathy
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic necrosis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic phlebitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic pulmonary embolism
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic rash
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic shock
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Septic vasculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Shunt infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sialoadenitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sinobronchitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sinusitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Skin graft infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Skin infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Soft tissue infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Southern tick-associated rash illness
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spermatic cord funiculitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spinal cord abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spinal cord infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spinal empyema
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sputum purulent
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sternitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stitch abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stoma site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Stoma site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subacute endocarditis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subarachnoid abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subcutaneous abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subdiaphragmatic abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subdural abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subgaleal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subglottic laryngitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Subperiosteal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Superinfection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sweat gland infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Systemic infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	TORCH infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Testicular abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thrombophlebitis septic
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thymus abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thyroglossal cyst infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thyroid gland abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tick-borne fever
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tongue abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tonsillitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tooth abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tooth infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tornwaldt bursitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Toxic shock syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheitis obstructive
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheobronchitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheostomy infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Transplant abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tropical infectious disease
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tropical ulcer
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tubo-ovarian abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Umbilical sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Upper aerodigestive tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Upper respiratory tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urachal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ureter abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ureteritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethral abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethral carbuncle
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethral discharge syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethral stricture post infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethritis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary bladder abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary meatitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection neonatal
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urosepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Uterine abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Uterine infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccination site abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccination site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccination site joint infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccination site pustule

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccine breakthrough infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaginal abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaginal infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vascular access site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vascular device infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vascular graft infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vessel puncture site infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vestibulitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viraemia
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Virologic failure
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Visceral larva migrans
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vitreous abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vitritis infective
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulval abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound abscess
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound sepsis
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Young's syndrome
Infections 'ALL'	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zoonosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adrenal gland tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Atypical mycobacterial infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Atypical mycobacterial lower respiratory tract infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Atypical mycobacterial lymphadenitis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Atypical mycobacterial pneumonia
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Atypical mycobacterium pericarditis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bone tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Borderline leprosy
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bovine tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Choroid tubercles
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis tuberculous
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated Bacillus Calmette-Guerin infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated mycobacterium avium complex infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epididymitis tuberculous
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erythema induratum
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Extrapulmonary tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Female genital tract tuberculosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Immune reconstitution inflammatory syndrome associated tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Indeterminate leprosy
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Intestinal tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Joint tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Latent tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lepromatous leprosy
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Leprosy
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lupus vulgaris
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymph node tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Male genital tract tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mammary tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis tuberculous
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterial infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterial peritonitis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium abscessus infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium avium complex immune restoration disease
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium avium complex infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium chelonae infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium fortuitum infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium haemophilum infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium kansasii infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium marinum infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycobacterium ulcerans infection
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oesophageal tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis tuberculous
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritoneal tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prostatitis tuberculous
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary tuberculoma
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pulmonary tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Renal tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Salpingitis tuberculous
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Silicotuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Spleen tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Superinfection mycobacterial
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Thyroid tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculoid leprosy
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculoma of central nervous system
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis bladder
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis gastrointestinal
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis liver
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis of central nervous system
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis of eye

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis of genitourinary system
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis of intrathoracic lymph nodes
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis of peripheral lymph nodes
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculosis ureter
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculous endometritis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculous laryngitis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculous pleurisy
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tuberculous tenosynovitis
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Type 1 lepra reaction
Infections 'ALL'	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Type 2 lepra reaction
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervicitis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epididymitis ureaplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycoplasma genitalium infection
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycoplasma infection
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycoplasmal postabortal fever
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mycoplasmal postpartum fever
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pelvic inflammatory disease mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngitis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelonephritis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheobronchitis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ureaplasma cervicitis
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ureaplasma infection
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ureaplasmal vulvovaginitis
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethritis mycoplasmal
Infections 'ALL'	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethritis ureaplasmal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Acid fast bacilli infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Acinetobacter sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Actinomycotic sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Acute pulmonary histoplasmosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Adenoviral encephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Adenoviral haemorrhagic cystitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Adenoviral meningitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Adenovirus encephalomyeloradiculitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Adrenal gland tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Alternaria infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Amoebic brain abscess
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Amoebic lung abscess
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Arthritis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Aspergillosis oral
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Aspergillus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial lower respiratory tract infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial lymphadenitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial pneumonia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterium pericarditis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		BK virus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Bacillary angiomatosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Biliary tract infection cryptosporidial
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Biliary tract infection fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Blastocystis infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Blastomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Bone tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Borderline leprosy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Bovine tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Bronchitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Bronchopulmonary aspergillosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Burkholderia cepacia complex sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Burkholderia gladioli infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Burkholderia pseudomallei infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Candida endophthalmitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Candida osteomyelitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Candida pneumonia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Candida retinitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Candida sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Candidiasis of trachea
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Capnocytophaga infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Capnocytophaga sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Central nervous system fungal infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Central nervous system viral infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cerebral aspergillosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cerebral fungal infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cerebral toxoplasmosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Choroid tubercles
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Chromoblastomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Chronic pulmonary histoplasmosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Coccidioides encephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Coccidioidomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Colitis herpes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Conjunctivitis tuberculous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cryptococcal cutaneous infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cryptococcal fungaemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cryptococcal meningoencephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cryptococcosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cryptosporidiosis infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cutaneous coccidioidomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cutaneous tuberculosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus chorioretinitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus colitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus duodenitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus enteritis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus enterocolitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastritis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastroenteritis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastrointestinal infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastrointestinal ulcer
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus hepatitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus infection reactivation
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus mononucleosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus mucocutaneous ulcer
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus myelomeningoradiculitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus myocarditis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus oesophagitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus pancreatitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus pericarditis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus syndrome
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus urinary tract infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus viraemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated aspergillosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated blastomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated coccidioidomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated cryptococcosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated cytomegaloviral infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated leishmaniasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated mucormycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated mycobacterium avium complex infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated paracoccidioidomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated sporotrichosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated strongyloidiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated toxoplasmosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated trichosporonosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated varicella
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated varicella zoster vaccine virus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Disseminated varicella zoster virus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Ear tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Encephalitis cytomegalovirus
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Encephalitis fungal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Encephalitis post varicella
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Endocarditis Q fever
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Endocarditis candida
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Endocarditis histoplasma
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Enterocolitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Epididymitis blastomyces
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Epididymitis tuberculous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Epstein-Barr virus associated lymphoproliferative disorder
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Epstein-Barr virus infection reactivation
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Exserohilum infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Extrapulmonary tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Eye infection toxoplasmal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Female genital tract tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Flavobacterium infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fournier's gangrene
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungaemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal abscess central nervous system
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal endocarditis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal labyrinthitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal oesophagitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal peritonitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal retinitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal rhinitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fungal tracheitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Fusarium infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Gastritis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Gastritis herpes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Gastroenteritis cryptococcal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Gastroenteritis cryptosporidial
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Gastrointestinal fungal infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Gastrointestinal mucormycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Hepatic candidiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Hepatic infection fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Hepatosplenic candidiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes oesophagitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes ophthalmic
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex bronchitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex colitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex encephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex gastritis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex hepatitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex meningitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex meningoencephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex meningomyelitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex necrotising retinopathy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex oesophagitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex otitis externa
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex pneumonia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex viraemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes simplex visceral
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster cutaneous disseminated
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster infection neurological
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningoencephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningomyelitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningoradiculitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster necrotising retinopathy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster oticus
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Herpes zoster pharyngitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Histoplasmosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Histoplasmosis cutaneous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Histoplasmosis disseminated
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Human herpesvirus 6 encephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Human herpesvirus 6 infection reactivation
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Human herpesvirus 8 infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Immune reconstitution inflammatory syndrome associated tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Indeterminate leprosy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Infection in an immunocompromised host
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Infection susceptibility increased
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Intestinal tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Isosporiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		JC virus CSF test positive
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		JC virus granule cell neuronopathy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		JC virus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Joint tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Kaposi's sarcoma
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Kaposi's sarcoma AIDS related
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Laryngeal cryptococcosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Laryngitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Lepromatous leprosy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Leprosy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Listeria encephalitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Listeria sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Listeriosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Lower respiratory tract herpes infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Lower respiratory tract infection fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Lupus vulgaris
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Lymph node tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Lymphadenitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Male genital tract tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mammary tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mastitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis aspergillus
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis candida
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis coccidioides
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis cryptococcal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis exserohilum
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis herpes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis histoplasma
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis listeria
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis toxoplasmal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningitis tuberculous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningoencephalitis herpetic
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Meningomyelitis herpes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Methylobacterium infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Microsporidia infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Miliary pneumonia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mucormycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycetoma mycotic
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterial infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterial peritonitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium abscessus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium avium complex immune restoration disease
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium avium complex infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium chelonae infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium fortuitum infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium kansasii infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium marinum infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycobacterium ulcerans infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Mycotic endophthalmitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Myocarditis mycotic
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Myocarditis toxoplasmal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Necrotising fasciitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Necrotising herpetic retinopathy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Neurocryptococcosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Nocardia sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Nocardiosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Oesophageal candidiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Oesophageal tuberculosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Ophthalmic herpes simplex
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Ophthalmic herpes zoster
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Opportunistic infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Oral tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Oro-pharyngeal aspergillosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Osteomyelitis blastomyces
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Osteomyelitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Otitis media fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pancreatitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Paracoccidioides infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Parvovirus B19 infection reactivation
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Penicillium infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pericarditis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pericarditis histoplasma
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pericarditis tuberculous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Peritoneal candidiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Peritoneal tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Phaeohyphomycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumocystis jirovecii infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumocystis jirovecii pneumonia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia blastomyces
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia cryptococcal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia cytomegaloviral
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia herpes viral
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia legionella
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pneumonia toxoplasmal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Polyomavirus viraemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Polyomavirus-associated nephropathy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Proctitis herpes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Progressive multifocal leukoencephalopathy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Progressive vaccinia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Prostatitis tuberculous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Protothecosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pseudallescheria infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pseudallescheria sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pseudomonas aeruginosa meningitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pulmonary mucormycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pulmonary nocardiosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pulmonary trichosporonosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pulmonary tuberculoma
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pulmonary tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Pyelonephritis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Renal tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Respiratory tract infection fungal

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Retinitis histoplasma
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Retinitis viral
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Rhinocerebral mucormycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Rhodococcus infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Salpingitis tuberculous
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Scedosporium infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Septic arthritis staphylococcal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Sinusitis aspergillus
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Sinusitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Sphingomonas paucimobilis bacteraemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Sphingomonas paucimobilis infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Spleen tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Splenic candidiasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Splenic infection fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Stenotrophomonas bacteraemia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Stenotrophomonas infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Stenotrophomonas sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Superinfection fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Superinfection mycobacterial
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Systemic candida
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Systemic mycosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Thyroid tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tonsillitis fungal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Toxoplasmosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculoid leprosy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculoma of central nervous system
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis bladder
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis gastrointestinal
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis liver
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis of central nervous system
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis of eye
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis of genitourinary system
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis of intrathoracic lymph nodes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis of peripheral lymph nodes
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculosis ureter
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculous abscess central nervous system
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculous endometritis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculous laryngitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculous pleurisy
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Tuberculous tenosynovitis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Upper respiratory fungal infection
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Varicella zoster gastritis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Varicella zoster oesophagitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Varicella zoster pneumonia
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Varicella zoster sepsis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Visceral leishmaniasis
Infections 'ALL'	Opportunistic infections (SMQ)	NARROW		Weissella infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acanthamoeba infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acanthamoeba keratitis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	African trypanosomiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	American trypanosomiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amoebiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amoebic brain abscess
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amoebic colitis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amoebic dysentery
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amoebic lung abscess
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Amoebic skin ulcer
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Babesiosis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Balamuthia infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Balantidiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary tract infection cryptosporidial
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Blackwater fever
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Blastocystis infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral malaria
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cerebral toxoplasmosis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervicitis trichomonal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chagas' cardiomyopathy
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chagoma
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital malaria
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital toxoplasmosis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cryptosporidiosis infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cutaneous leishmaniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cyclosporidium infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dientamoeba infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated leishmaniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated toxoplasmosis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis protozoal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection toxoplasmal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis cryptosporidial
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal protozoal infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Giardiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatic amoebiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis toxoplasmal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infection protozoal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Isosporiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Leishmaniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malaria
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malaria recrudescence
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malaria relapse

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Malarial myocarditis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis toxoplasmal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis trypanosomal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningoencephalitis amoebic
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Microsporidia infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mucocutaneous leishmaniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Myocarditis toxoplasmal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Naegleria infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pericarditis amoebic
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plasmodium falciparum infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plasmodium knowlesi infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plasmodium malariae infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plasmodium ovale infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Plasmodium vivax infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia toxoplasmal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prostatitis trichomonal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Protothecosis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Protozoal corneal ulcer
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Romana's sign
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sarcocystis infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Toxoplasmosis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichomoniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trichomoniasis intestinal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Trypanosomiasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethritis trichomonal
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urogenital trichomoniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Visceral leishmaniasis
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vorticella infection
Infections 'ALL'	Protozoal infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginitis trichomonal
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Boutonneuse fever
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxiella infection
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis rickettsial
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis Q fever
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epidemic typhus
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human anaplasmosis
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human ehrlichiosis
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Japanese spotted fever
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Murine typhus
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	North Asian tick typhus
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Q fever
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Queensland tick typhus
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Recrudescent typhus
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rickettsialpox
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rickettsioses not tick borne
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rickettsiosis
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rocky mountain spotted fever

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Scrub typhus
Infections 'ALL'	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Typhus
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Adrenal gland tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Bone tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Bovine tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Choroid tubercles
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Congenital tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Conjunctivitis tuberculous
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Cutaneous tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Disseminated Bacillus Calmette-Guerin infection
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Disseminated tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Ear tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Epididymitis tuberculous
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Erythema induratum
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Extrapulmonary tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Female genital tract tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Immune reconstitution inflammatory syndrome associated tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Interferon gamma release assay positive
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Intestinal tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Joint tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Latent tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Lupus vulgaris
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Lymph node tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Male genital tract tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Mammary tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Meningitis tuberculous
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Miliary pneumonia
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Mycobacterium tuberculosis complex test positive
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Oesophageal tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Oral tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Pericarditis tuberculous
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Peritoneal tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Prostatitis tuberculous
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Pulmonary tuberculoma
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Pulmonary tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Renal tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Salpingitis tuberculous
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Silicotuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Spleen tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Thyroid tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculid
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculin test false negative
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculin test positive

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculoma of central nervous system
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis bladder
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis gastrointestinal
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis liver
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of central nervous system
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of eye
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of genitourinary system
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of intrathoracic lymph nodes
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of peripheral lymph nodes
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis ureter
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous abscess central nervous system
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous endometritis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous laryngitis
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous pleurisy
Infections 'ALL'	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous tenosynovitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	AIDS cholangiopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	AIDS dysmorphic syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	AIDS related complex
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	AIDS related complication
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	AIDS retinopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acquired immunodeficiency syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute HIV infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute haemorrhagic conjunctivitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute hepatitis B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Acute hepatitis C
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoviral conjunctivitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoviral encephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoviral haemorrhagic cystitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoviral hepatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoviral meningitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenoviral upper respiratory infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenovirus encephalomyeloradiculitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Adenovirus reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alongshan virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Alphaviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anogenital warts
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Anorectal human papilloma virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arboviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arenaviral haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Argentine haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis rubella

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Arthritis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Asymptomatic COVID-19
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Asymptomatic HIV infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Asymptomatic viral hepatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Avian influenza
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	BK virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Biliary tract infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Blepharal papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bolivian haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Boston exanthema
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bovine pustular stomatitis virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchiolitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bronchitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Bulbar poliomyelitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Buschke-Lowenstein's tumour
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	COVID-19
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	COVID-19 pneumonia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	CSF HIV escape syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cataract congenital
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Central nervous system enteroviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Central nervous system viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervicitis human papilloma virus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cervix warts
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chikungunya virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Choriomeningitis lymphocytic
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic active Epstein-Barr virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic hepatitis B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Chronic hepatitis C
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Colitis herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Colorado tick fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital COVID-19
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital Ebola virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital HIV infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital Zika syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital condyloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital cytomegalovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital dengue disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital hepatitis B infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital hepatitis C infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital herpes simplex infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital rubella infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital rubella syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital varicella infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congenital viral hepatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Congo-Crimean haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Conjunctivitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coronavirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cow pox
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie bronchitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie carditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie endocarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie myocarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie pericarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie viral disease of the newborn
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Coxsackie viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Creutzfeldt-Jakob disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cystitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus chorioretinitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus colitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus duodenitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus enteritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus enterocolitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus gastritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus gastroenteritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus gastrointestinal infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus gastrointestinal ulcer
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus hepatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus infection reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus mononucleosis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus mucocutaneous ulcer
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus myelomeningoradiculitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus myocarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus nephritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus oesophagitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus pancreatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus pericarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus urinary tract infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Cytomegalovirus viraemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dengue fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Dengue haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated cytomegaloviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated neonatal herpes simplex
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated varicella
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated varicella zoster vaccine virus infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Disseminated varicella zoster virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ear infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ebola Reston virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ebola disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Echo virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eczema Coxsackium
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eczema herpeticum
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eczema vaccinatum
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis Japanese B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis australia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis california
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis cytomegalovirus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis eastern equine
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis enteroviral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis influenzal
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis venezuelan equine
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalitis western equine
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Encephalomyelitis rubella
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	End stage AIDS
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Endocarditis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterocolitis AIDS
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterocolitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Enterovirus myocarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epidemic pleurodynia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epidemic polyarthritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epidermodysplasia verruciformis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epididymitis mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epstein Barr virus positive mucocutaneous ulcer
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epstein-Barr viraemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epstein-Barr virus associated lymphoma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epstein-Barr virus associated lymphoproliferative disorder
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epstein-Barr virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Epstein-Barr virus infection reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eruptive pseudoangiomatosis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Erythema infectiosum
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Exanthema subitum
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Eye infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Fatal familial insomnia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Filovirus infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Flavivirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Focal epithelial hyperplasia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Foot and mouth disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastritis herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastritis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis adenovirus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis astroviral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis caliciviral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis enteroviral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis norovirus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis rotavirus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis sapovirus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastroenteritis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gastrointestinal viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Generalised vaccinia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital herpes simplex
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital herpes zoster
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Genital infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gerstmann Straussler Scheinker syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Gianotti-Crosti syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	H1N1 influenza
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	H2N2 influenza
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	H3N2 influenza
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HCoV-229E infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HCoV-HKU1 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HCoV-NL63 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HCoV-OC43 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV associated nephropathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV cardiomyopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV enteropathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group I
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group II
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group III
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group IV subgroup A
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group IV subgroup B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group IV subgroup C1
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group IV subgroup C2
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group IV subgroup D
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC Group IV subgroup E
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC category A
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC category B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC category C
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection CDC group IV
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection WHO clinical stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection WHO clinical stage II
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection WHO clinical stage III
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV infection WHO clinical stage IV
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV lipodystrophy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV meningoencephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV peripheral neuropathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV viraemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV wasting syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV-2 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	HIV-associated neurocognitive disorder
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemorrhagic fever with renal syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Haemorrhagic varicella syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hand-foot-and-mouth disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hantaviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hantavirus pulmonary infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Heartland virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis A
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis B reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis C
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis D
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis E
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis F
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis G
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis H
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis infectious mononucleosis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis non-A non-B
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis non-A non-B non-C
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Hepatitis virus-associated nephropathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpangina
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes dermatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes oesophagitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes ophthalmic
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes pharyngitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes sepsis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex bronchitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex cervicitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex colitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex encephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex gastritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex hepatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex meningitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex meningoencephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex meningomyelitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex necrotising retinopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex oesophagitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex otitis externa
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex pharyngitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex pneumonia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex sepsis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex viraemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex virus conjunctivitis neonatal
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes simplex visceral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster cutaneous disseminated
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster infection neurological
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster meningitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster meningoencephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster meningomyelitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster meningoradiculitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster necrotising retinopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster oticus
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster pharyngitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpes zoster reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Herpetic radiculopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human T-cell lymphocytic virus type II infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human T-cell lymphotropic virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human T-cell lymphotropic virus type I infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human bocavirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human herpesvirus 6 encephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human herpesvirus 6 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human herpesvirus 6 infection reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human herpesvirus 7 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human herpesvirus 8 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Human polyomavirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Infectious mononucleosis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Influenza
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	JC virus granule cell neuronopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	JC virus infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kaposi sarcoma inflammatory cytokine syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kaposi's sarcoma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kaposi's sarcoma AIDS related
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Keratoconjunctivitis measles
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kuru
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Kyasanur Forest disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngeal papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Laryngitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lassa fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Louping ill
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lower respiratory tract herpes infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lower respiratory tract infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lujo haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphadenitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Lymphoma AIDS related
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Marburg disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Measles
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Measles meningitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Measles post vaccine
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis coxsackie viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis echo viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis enteroviral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningoencephalitis herpes simplex neonatal
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningoencephalitis herpetic
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningoencephalitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Meningomyelitis herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Merkel cell polyomavirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Metapneumovirus bronchiolitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Metapneumovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Metapneumovirus pneumonia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Middle East respiratory syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Milker's nodules
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Molluscum contagiosum
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Monkeypox
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Mumps deafness
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Murray Valley encephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nail bed infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nasal herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Necrotising herpetic retinopathy

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Neonatal mucocutaneous herpes simplex
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Newcastle disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Nipah virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Norovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	O'nyong-nyong fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Omsk haemorrhagic fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ophthalmic herpes simplex
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Ophthalmic herpes zoster
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral hairy leukoplakia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oral viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Orbivirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Orchitis mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Orf
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Oropouche fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Orthopox virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Osteomyelitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis externa viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media post measles
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Otitis media viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreatitis mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pancreatitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Papilloma viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Papular pruritic eruption of HIV
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parainfluenzae viral bronchitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parainfluenzae viral laryngotracheobronchitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parainfluenzae virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parapox virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Paravaccinia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parechovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parvovirus B19 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parvovirus B19 infection reactivation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Parvovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Penile wart
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perinatal HBV infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Perinatal HIV infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Peritonitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Persistent generalised lymphadenopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pharyngoconjunctival fever of children
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Phlebotomus fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Picornavirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pleurisy viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia adenoviral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia cytomegaloviral

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia herpes viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia influenzal
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia measles
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia parainfluenzae viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia respiratory syncytial viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pneumonia viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pogosta disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Polioencephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Poliomyelitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Polyneuropathy mumps
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Polyomavirus viraemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Polyomavirus-associated nephropathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post measles blindness
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post transplant lymphoproliferative disorder
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post vaccination autoinoculation
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post viral fatigue syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Post-acute COVID-19 syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Prion disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Proctitis herpes
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Progressive multifocal leukoencephalopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Progressive vaccinia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Pyelonephritis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rabies
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Reoviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory syncytial virus bronchiolitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory syncytial virus bronchitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory syncytial virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Respiratory tract infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retinitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retroviral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Retroviral rebound syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rhinovirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rift Valley fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rocio virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rotavirus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rubella
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rubella in pregnancy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Rubella infection neurological
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	SARS-CoV-2 sepsis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	SARS-CoV-2 viraemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Severe acute respiratory syndrome

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Severe fever with thrombocytopenia syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sinonasal papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Skin papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Slow virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Smallpox
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Snowshoe hare virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Splenic infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	St. Louis encephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Superinfection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Suspected COVID-19
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Sweating fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Systemic viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	T-cell lymphoma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	T-cell type acute leukaemia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tick-borne viral encephalitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheal papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tracheobronchitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Tropical spastic paresis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urethral papilloma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Urinary tract infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccine associated paralytic poliomyelitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccine derived SARS-CoV-2 infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaccinia virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vaginitis viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Variant Creutzfeldt-Jakob disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella keratitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella post vaccine
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella zoster gastritis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella zoster oesophagitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella zoster pneumonia
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella zoster sepsis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Varicella zoster virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vestibular neuronitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral acanthoma
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral cardiomyopathy
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral corneal ulcer
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral diarrhoea
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral epiglottitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral haemorrhagic cystitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral keratouveitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral labyrinthitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral mastitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral myelitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral myocarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral myositis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral oesophagitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral parotitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral pericarditis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral pharyngitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral rash
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral rhinitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral sepsis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral sinusitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral skin infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral tonsillitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral tracheitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral upper respiratory tract infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral uveitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Viral vasculitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginal human papilloma virus infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Vulvovaginal warts
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	West Nile viral infection
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Withdrawal hepatitis
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Wound infection viral
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	X-linked lymphoproliferative syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yellow fever
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yellow fever vaccine-associated neurotropic disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Yellow fever vaccine-associated viscerotropic disease
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zika virus associated Guillain Barre syndrome
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zika virus associated birth defect
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zika virus associated microencephaly
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zika virus associated ocular birth defect
Infections 'ALL'	Viral infectious disorders (HLGT)		ASER eq 'Yes' or ATOXGRN ge 3	Zika virus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Acid fast bacilli infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Acinetobacter sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Actinomycotic sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Acute pulmonary histoplasmosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Adenoviral encephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Adenoviral haemorrhagic cystitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Adenoviral meningitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Adenovirus encephalomyeloradiculitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Adrenal gland tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Alternaria infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Amoebic brain abscess
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Amoebic lung abscess
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Arthritis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Aspergillosis oral
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Aspergillus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial lower respiratory tract infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial lymphadenitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterial pneumonia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Atypical mycobacterium pericarditis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		BK virus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Bacillary angiomatosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Biliary tract infection cryptosporidial
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Biliary tract infection fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Blastocystis infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Blastomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Bone tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Borderline leprosy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Bovine tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Bronchitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Bronchopulmonary aspergillosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Burkholderia cepacia complex sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Burkholderia gladioli infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Burkholderia pseudomallei infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Candida endophthalmitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Candida osteomyelitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Candida pneumonia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Candida retinitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Candida sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Candidiasis of trachea
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Capnocytophaga infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Capnocytophaga sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Central nervous system fungal infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Central nervous system viral infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cerebral aspergillosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cerebral fungal infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cerebral toxoplasmosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Choroid tubercles
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Chromoblastomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Chronic pulmonary histoplasmosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Coccidioides encephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Coccidioidomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Colitis herpes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Conjunctivitis tuberculous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cryptococcal cutaneous infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cryptococcal fungaemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cryptococcal meningoencephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cryptococcosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cryptosporidiosis infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cutaneous coccidioidomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cutaneous tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus chorioretinitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus colitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus duodenitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus enteritis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus enterocolitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastritis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastroenteritis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastrointestinal infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus gastrointestinal ulcer
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus hepatitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus infection reactivation
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus mononucleosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus mucocutaneous ulcer
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus myelomeningoradiculitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus myocarditis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus oesophagitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus pancreatitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus pericarditis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus syndrome
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus urinary tract infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Cytomegalovirus viraemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated aspergillosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated blastomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated coccidioidomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated cryptococcosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated cytomegaloviral infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated leishmaniasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated mucormycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated mycobacterium avium complex infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated paracoccidioidomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated sporotrichosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated strongyloidiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated toxoplasmosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated trichosporonosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated varicella

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated varicella zoster vaccine virus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Disseminated varicella zoster virus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Ear tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Encephalitis cytomegalovirus
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Encephalitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Encephalitis post varicella
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Endocarditis Q fever
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Endocarditis candida
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Endocarditis histoplasma
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Enterocolitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Epididymitis blastomyces
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Epididymitis tuberculous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Epstein-Barr virus associated lymphoproliferative disorder
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Epstein-Barr virus infection reactivation
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Exserohilum infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Extrapulmonary tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Eye infection toxoplasmal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Female genital tract tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Flavobacterium infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fournier's gangrene
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungaemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal abscess central nervous system
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal endocarditis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal labyrinthitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal oesophagitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal peritonitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal retinitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal rhinitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fungal tracheitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Fusarium infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Gastritis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Gastritis herpes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Gastroenteritis cryptococcal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Gastroenteritis cryptosporidial
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Gastrointestinal fungal infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Gastrointestinal mucormycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Hepatic candidiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Hepatic infection fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Hepatosplenic candidiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes oesophagitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes ophthalmic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex bronchitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex colitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex encephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex gastritis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex hepatitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex meningitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex meningoencephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex meningomyelitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex necrotising retinopathy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex oesophagitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex otitis externa
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex pneumonia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex viraemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes simplex visceral
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster cutaneous disseminated
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster infection neurological
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningoencephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningomyelitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster meningoradiculitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster necrotising retinopathy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster oticus
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Herpes zoster pharyngitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Histoplasmosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Histoplasmosis cutaneous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Histoplasmosis disseminated
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Human herpesvirus 6 encephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Human herpesvirus 6 infection reactivation
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Human herpesvirus 8 infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Immune reconstitution inflammatory syndrome associated tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Indeterminate leprosy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Infection in an immunocompromised host
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Infection susceptibility increased
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Intestinal tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Isosporiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		JC virus CSF test positive
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		JC virus granule cell neuronopathy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		JC virus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Joint tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Kaposi’s sarcoma
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Kaposi’s sarcoma AIDS related
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Laryngeal cryptococcosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Laryngitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Lepromatous leprosy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Leprosy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Listeria encephalitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Listeria sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Listeriosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Lower respiratory tract herpes infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Lower respiratory tract infection fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Lupus vulgaris
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Lymph node tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Lymphadenitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Male genital tract tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mammary tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mastitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis aspergillus
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis candida
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis coccidioides
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis cryptococcal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis exserohilum
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis herpes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis histoplasma
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis listeria
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis toxoplasmal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningitis tuberculous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningoencephalitis herpetic
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Meningomyelitis herpes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Methylobacterium infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Microsporidia infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Miliary pneumonia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mucormycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycetoma mycotic
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterial infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterial peritonitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium abscessus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium avium complex immune restoration disease
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium avium complex infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium chelonae infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium fortuitum infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium kansasii infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium marinum infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycobacterium ulcerans infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Mycotic endophthalmitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Myocarditis mycotic
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Myocarditis toxoplasmal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Necrotising fasciitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Necrotising herpetic retinopathy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Neurocryptococcosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Nocardia sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Nocardiosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Oesophageal candidiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Oesophageal tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Ophthalmic herpes simplex
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Ophthalmic herpes zoster
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Opportunistic infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Oral tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Oro-pharyngeal aspergillosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Osteomyelitis blastomyces
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Osteomyelitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Otitis media fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pancreatitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Paracoccidioides infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Parvovirus B19 infection reactivation
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Penicillium infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pericarditis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pericarditis histoplasma
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pericarditis tuberculous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Peritoneal candidiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Peritoneal tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Phaeohyphomycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumocystis jirovecii infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumocystis jirovecii pneumonia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia blastomyces
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia cryptococcal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia cytomegaloviral
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia herpes viral
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia legionella
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pneumonia toxoplasmal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Polyomavirus viraemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Polyomavirus-associated nephropathy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Proctitis herpes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Progressive multifocal leukoencephalopathy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Progressive vaccinia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Prostatitis tuberculous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Protothecosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pseudallescheria infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pseudallescheria sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pseudomonas aeruginosa meningitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pulmonary mucormycosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pulmonary nocardiosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pulmonary trichosporonosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pulmonary tuberculoma
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pulmonary tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Pyelonephritis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Renal tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Respiratory tract infection fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Retinitis histoplasma
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Retinitis viral
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Rhinocerebral mucormycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Rhodococcus infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Salpingitis tuberculous
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Scedosporium infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Septic arthritis staphylococcal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Sinusitis aspergillus
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Sinusitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Sphingomonas paucimobilis bacteraemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Sphingomonas paucimobilis infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Spleen tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Splenic candidiasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Splenic infection fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Stenotrophomonas bacteraemia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Stenotrophomonas infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Stenotrophomonas sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Superinfection fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Superinfection mycobacterial
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Systemic candida
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Systemic mycosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Thyroid tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tonsillitis fungal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Toxoplasmosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculoid leprosy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculoma of central nervous system
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis bladder
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis gastrointestinal
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis liver
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis of central nervous system
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis of eye
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis of genitourinary system
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis of intrathoracic lymph nodes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis of peripheral lymph nodes
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculosis ureter
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculous abscess central nervous system

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculous endometritis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculous laryngitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculous pleurisy
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Tuberculous tenosynovitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Upper respiratory fungal infection
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Varicella zoster gastritis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Varicella zoster oesophagitis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Varicella zoster pneumonia
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Varicella zoster sepsis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Visceral leishmaniasis
Opportunistic infections	Opportunistic infections (SMQ)	NARROW		Weissella infection
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Adrenal gland tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Bone tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Bovine tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Choroid tubercles
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Congenital tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Conjunctivitis tuberculous
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Cutaneous tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Disseminated Bacillus Calmette-Guerin infection
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Disseminated tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Ear tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Epididymitis tuberculous
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Erythema induratum
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Extrapulmonary tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Female genital tract tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Immune reconstitution inflammatory syndrome associated tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Interferon gamma release assay positive
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Intestinal tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Joint tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Latent tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Lupus vulgaris
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Lymph node tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Male genital tract tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Mammary tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Meningitis tuberculous
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Miliary pneumonia
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Mycobacterium tuberculosis complex test positive
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Oesophageal tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Oral tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Pericarditis tuberculous
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Peritoneal tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Prostatitis tuberculous
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Pulmonary tuberculoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Pulmonary tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Renal tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Salpingitis tuberculous
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Silicotuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Spleen tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Thyroid tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculid
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculin test false negative
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculin test positive
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculoma of central nervous system
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis bladder
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis gastrointestinal
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis liver
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of central nervous system
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of eye
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of genitourinary system
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of intrathoracic lymph nodes
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis of peripheral lymph nodes
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculosis ureter
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous abscess central nervous system
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous endometritis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous laryngitis
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous pleurisy
Tuberculosis infections	Tuberculosis related terms (BIcMQ)	NARROW		Tuberculous tenosynovitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Acute encephalitis with refractory, repetitive partial seizures
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Acute motor axonal neuropathy
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Acute motor-sensory axonal neuropathy
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Air-borne transmission
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Arthritis reactive
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Arthropod-borne disease
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Axonal and demyelinating polyneuropathy
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Bacterial disease carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Bickerstaff's encephalitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Bullous oedema of the bladder
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Chronic gastritis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Chronic hepatitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Ciliary ganglionitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Community acquired infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Cutaneous malacoplakia
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Degenerative multivalvular disease
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Diphtheria carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Direct infection transmission

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Encephalitis post immunisation
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Encephalitis post varicella
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Endocarditis rheumatic
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Erythema marginatum
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Faecal-oral transmission of infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Febrile infection-related epilepsy syndrome
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Follicular cystitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Food poisoning
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Fungal disease carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Granulomatous lymphadenitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Guillain-Barre syndrome
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	HIV carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	HTLV-1 carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Hepatitis chronic active
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Hepatitis chronic persistent
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Hepatitis fulminant
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Human immunodeficiency virus transmission
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Iatrogenic infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Indirect infection transmission
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Infantile acropustulosis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Infection transmission via personal contact
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Infection via vaccinee
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Infectious disease carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Kawasaki's disease
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Keratoderma blenorrhagica
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Malacoplakia
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Malacoplakia gastrointestinal
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Malacoplakia of bone
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Malacoplakia vesicae
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Multisystem inflammatory syndrome in children
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Mycobacterial disease carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Myocarditis post infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Nosocomial infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Pericarditis rheumatic
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Poncet's disease
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Post herpetic neuralgia
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Post infection glomerulonephritis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Post polio syndrome
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Post streptococcal glomerulonephritis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Primary transmission
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Progressive massive fibrosis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Psorospermiasis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Reye's syndrome
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Rheumatic fever
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Rheumatic heart disease
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Roseola
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	SARS-CoV-2 carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	SJS-TEN overlap
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Scleroedema
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Secondary amyloidosis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Secondary transmission
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Sexual transmission of infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Sexually transmitted disease
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Sexually transmitted disease carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Sporadic infantile bilateral striatal necrosis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Stevens-Johnson syndrome
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Subacute inflammatory demyelinating polyneuropathy
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Subacute sclerosing panencephalitis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Suspected transmission of an infectious agent via product
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Sydenham's chorea
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Thyroiditis subacute
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Tick paralysis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Toxic epidermal necrolysis
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Transmission of an infectious agent via product
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Transmission of an infectious agent via transplant
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Typhoid carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Vaccine bacteria shedding
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Vaccine virus shedding
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Vector-borne transmission of infection
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Vertical infection transmission
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Viral disease carrier
Serious infections	Ancillary infectious topics (HLGT)		ASER eq 'Yes'	Viral hepatitis carrier
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Abdominal hernia gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Abscess bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Achromobacter infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Acid fast bacilli infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Acinetobacter bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Acinetobacter infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Acinetobacter sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Acrodermatitis chronica atrophicans

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Actinomycosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Actinomycotic abdominal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Actinomycotic pulmonary infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Actinomycotic sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Actinomycotic skin infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Adenopathy syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Administration site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Aerococcus urinae infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Aeromonas infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Alcaligenes infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Alopecia syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Alpha haemolytic streptococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Angina gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Anicteric leptospirosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Anorectal cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Anorectal infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Anthrax
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Anthrax sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Antibiotic associated colitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Aortic aneurysm syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Aortitis salmonella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Aortitis syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Application site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Arteriosclerotic gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Arthritis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Arthritis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Arthritis salmonella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Asymptomatic bacteriuria
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacillary angiomatosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacillus bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacillus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterascites
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial abdominal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial abscess central nervous system
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial allergy
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial blepharitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial colitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial dacryocystitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial diarrhoea
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial endophthalmitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial food poisoning
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial gingivitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial iritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial labyrinthitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial myositis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial parotitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial pericarditis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial prostatitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial pyelonephritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial rhinitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial salpingitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial tracheitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial ureteritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial urethritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial vaginosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacterial vulvovaginitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacteriuria
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacteriuria in pregnancy
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bacteroides infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bartonellosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Beta haemolytic streptococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bifidobacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Biliary tract infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bordetella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Borrelia infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Botryomycosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Botulism
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Brachyspira infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Brazilian purpuric fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Breast cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Brevibacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis moraxella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis pneumococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Brucella sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Brucellosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bubonic plague
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bullous erysipelas
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bullous impetigo
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Burkholderia cepacia complex infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Burkholderia cepacia complex sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Burkholderia gladioli infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Burkholderia infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Burkholderia mallei infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Burkholderia pseudomallei infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bursitis infective staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Campylobacter colitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Campylobacter gastroenteritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Campylobacter infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Campylobacter sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Campylobacter urinary tract infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Capnocytophaga infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Capnocytophaga sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cardiovascular syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cat scratch disease
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Catheter site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis enterococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis of male external genital organ
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis orbital
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis pasteurella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cellulitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cerebral aneurysm ruptured syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cervicitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cervicitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Chancroid
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cholera
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Citrobacter bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Citrobacter infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Citrobacter sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Clostridial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Clostridial sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Clostridium bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Clostridium colitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Clostridium difficile colitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Clostridium difficile infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Colon gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Condyloma latum
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Congenital syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Congenital syphilitic encephalitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Congenital syphilitic meningitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Congenital syphilitic osteochondritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Conjunctivitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Conjunctivitis gonococcal neonatal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Corynebacterium bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Corynebacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Corynebacterium sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cronobacter bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cronobacter infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cronobacter necrotising enterocolitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous anthrax
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous listeriosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous nocardiosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cystitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cystitis escherichia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cystitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cystitis klebsiella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cystitis pseudomonal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Delftia acidovorans infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Diabetic gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Diaphragmatic hernia gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Diphtheria
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Ear infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Ear infection staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Eczema impetiginous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Empedobacter brevis infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis meningococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endemic syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis enterococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis meningococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis pseudomonal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endometritis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Endometritis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enteritis necroticans
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterobacter bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterobacter infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterobacter pneumonia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterobacter sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterobacter tracheobronchitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterococcal bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterococcal gastroenteritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterococcal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Enterocolitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Epididymo-orchitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Epiglottitis haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Erysipelas
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Erysipelothrix infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Erysipelothrix sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Erythema migrans
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Erythrasma
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia peritonitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia pyelonephritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia urinary tract infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Escherichia vaginitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Eubacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	External ear cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Femoral hernia gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Flavobacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Folliculitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Furuncle
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Fusobacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gangrene neonatal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gangrenous balanitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gardnerella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gas gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastric ulcer helicobacter
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastritis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis Escherichia coli
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis aerobacter
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis aeromonas
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis bacillus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis clostridial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis listeria
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis paracolon bacillus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis proteus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis pseudomonas
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis salmonella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis shigella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis vibrio
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis yersinia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal anthrax
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal bacterial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal bacterial overgrowth
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Genital infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Genitourinary tract gonococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Giant fornix syndrome
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gonococcal heart disease

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gonococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gonococcal pelvic inflammatory disease
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Gonorrhoea
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Granulicatella bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Granulicatella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Granuloma inguinale
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Group B streptococcus neonatal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Haemophilus bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Haemophilus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Haemophilus sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Helicobacter duodenal ulcer
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Helicobacter duodenitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Helicobacter gastritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Helicobacter infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Helicobacter sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Hepatic gas gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Hepatic infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Hernia gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Ileal gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Implant site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Incision site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Incisional hernia gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Infusion site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Inguinal hernia gangrenous
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Injection site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Intestinal gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Janeway lesion
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Jejunal gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Keratitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Keratosis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Klebsiella bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Klebsiella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Klebsiella sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lacrimal sac cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lactobacillus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Laryngitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Latent syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Legionella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lemierre syndrome
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Leptospira sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Leptospirosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Leptotrichia infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Leuconostoc infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lineal gingival erythema
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Listeraemia

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Listeria encephalitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Listeria sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Listeriosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lower respiratory tract infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lyme carditis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lyme disease
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lymphadenitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Malignant syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mastitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Medical device site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis Escherichia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis borrelia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis cronobacter
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis enterococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis leptospiral
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis listeria
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis meningococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis pneumococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis salmonella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningococcal bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningococcal carditis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningococcal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningoencephalitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Methylobacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Micrococcal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Micrococcus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Moraxella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Morganella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Myocarditis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Myocarditis meningococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Myocarditis syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Nail bed infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Necrobacillosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Necrotising fasciitis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Necrotising fasciitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Necrotising ulcerative gingivostomatitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Necrotising ulcerative periodontitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Neisseria infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Nephritis bacterial

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Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Neuroborreliosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Neurosyphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Nocardia sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Nocardiosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Oesophagitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Optic neuritis meningococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Oral bacterial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Oropharyngeal gonococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Osler's nodes
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Osteomyelitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Osteomyelitis salmonella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Otitis externa bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media moraxella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media pneumococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Ovarian bacterial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Overgrowth bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pancreatitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pantoea agglomerans infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Paratyphoid fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Paronychia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Parvimonas infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Parvimonas micra infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pasteurella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Penile gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peptic ulcer helicobacter
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peptostreptococcus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Perianal streptococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis meningococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Perichondritis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Perihepatitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Periorbital cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Periporitis staphylogenes
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peritonitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peritonitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peritonitis pneumococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peritonitis syphilitic
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pertussis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peruvian wart
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pharyngitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pharyngitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pinta

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Plague
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Plague sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pleural infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumococcal bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumococcal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia acinetobacter
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia anthrax
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia bordetella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia escherichia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia klebsiella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia legionella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia moraxella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia pneumococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia proteus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia pseudomonal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia salmonella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia serratia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia tularaemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonic plague
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pontiac fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Porphyromonas infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Post procedural cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Post treatment Lyme disease syndrome
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Primary syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Propionibacterium infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Prostatitis Escherichia coli
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Prostatitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Proteus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Providencia infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Providencia urinary tract infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomembranous colitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonal bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonal skin infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonas aeruginosa meningitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonas bronchitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonas infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pseudomonas peritonitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary nocardiosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Puncture site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Purple urine bag syndrome
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pyoderma streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pyomyositis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Raoultella ornithinolytica infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Relapsing fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Renal syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory tract infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Rhinoscleroma
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Rhodococcus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Salmonella bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Salmonella sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Salmonellosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Salpingitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Scarlet fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Scrotal gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Secondary syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Seminal vesiculitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Sepsis pasteurella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Septic arthritis haemophilus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Septic arthritis neisserial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Septic arthritis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Septic arthritis streptobacillus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Septic arthritis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Serratia bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Serratia infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Serratia sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Severe invasive streptococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Shewanella algae bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Shigella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Shigella sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Sinusitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Skin bacterial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Small intestine gangrene
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Sphingomonas paucimobilis bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Sphingomonas paucimobilis infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Spirillary fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Spirochaetal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Splenic infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal abscess
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal blepharitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal impetigo
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal mediastinitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal osteomyelitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal parotitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal pharyngitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal scalded skin syndrome
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal skin infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Staphylococcal toxaemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Stenotrophomonas bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Stenotrophomonas infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Stenotrophomonas sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Stoma site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Stomatococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptobacillary fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptobacillus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal abscess
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal bronchitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal endocarditis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal impetigo
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Streptococcal urinary tract infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Superinfection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Sycosis barbae
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Syphilis anal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Syphilis genital
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Syphilis musculoskeletal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Syphilitic endocarditis of heart valve
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Systemic bacterial infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Systemic bartonellosis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tertiary syphilis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tetanus
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tetanus neonatorum
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tonsillitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tonsillitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Toxic shock syndrome staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Toxic shock syndrome streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tracheobronchitis bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Trench fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculous abscess central nervous system
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tularaemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Typhoid fever
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Umbilical hernia gangrenous

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Upper respiratory tract infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Urethritis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract infection enterococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract infection pseudomonal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract infection staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Urogenital infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vaccination site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vaginal cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vaginitis gardnerella
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Veillonella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vessel puncture site cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vibrio vulnificus infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vulval cellulitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginitis gonococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginitis staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginitis streptococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Waterhouse-Friderichsen syndrome
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Weil's disease
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Weissella infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Whipple's disease
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Wound infection bacterial
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Wound infection pseudomonas
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Wound infection staphylococcal
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yaws
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yaws of bone
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yaws of skin
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yersinia bacteraemia
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yersinia infection
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yersinia meningitis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Yersinia sepsis
Serious infections	Bacterial infectious disorders (HLGT)		ASER eq 'Yes'	Zoonotic bacterial infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Anal chlamydia infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Chlamydial cervicitis
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Chlamydial infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Chlamydial pelvic inflammatory disease
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Conjunctivitis chlamydial
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection chlamydial
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Genitourinary chlamydia infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Gynaecological chlamydia infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Inclusion conjunctivitis
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Inclusion conjunctivitis neonatal
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Lymphogranuloma venereum
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Peritoneal chlamydia infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Pharyngeal chlamydia infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia chlamydial
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis chlamydial
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Psittacosis
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory tract chlamydial infection
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Trachoma
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Urethritis chlamydial
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Vaginitis chlamydial
Serious infections	Chlamydial infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginitis chlamydial
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Acariasis
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Acarodermatitis
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Arthropod infestation
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Bed bug infestation
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Demodicidosis
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Flea infestation
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Hirudiniasis
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Infestation
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Lice infestation
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Myiasis
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Trombidiasis
Serious infections	Ectoparasitic disorders (HLGT)		ASER eq 'Yes'	Tungiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Abscess fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Acute pulmonary histoplasmosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Allergic bronchopulmonary mycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Allescheriosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Alternaria infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Anal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Anal fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Anal tinea
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Arthritis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Aspergilloma
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Aspergillosis oral
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Aspergillus infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Aureobasidium pullulans infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Balanitis candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Biliary tract infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Black piedra
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Bladder candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Blastomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Body tinea
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Bronchopulmonary aspergillosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Bronchopulmonary aspergillosis allergic
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida cervicitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida endophthalmitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida nappy rash

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida osteomyelitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida pneumonia
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida retinitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida sepsis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candida urethritis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Candidiasis of trachea
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Central nervous system fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cerebral aspergillosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cerebral candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cerebral fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Chromoblastomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Chronic pulmonary histoplasmosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Coccidioides encephalitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Coccidioidomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Conjunctivitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cryptococcal cutaneous infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cryptococcal fungaemia
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cryptococcal meningoencephalitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cryptococcosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous blastomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous coccidioidomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous mucormycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous sporotrichosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Denture stomatitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Dermatophytosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Dermatophytosis of nail
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated aspergillosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated blastomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated coccidioidomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated cryptococcosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated mucormycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated paracoccidioidomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated sporotrichosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated trichosporonosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Ear infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis histoplasma
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Enterocolitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Epididymitis blastomyces
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Exserohilum infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal abscess central nervous system
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal balanitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal cystitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal endocarditis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal labyrinthitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal oesophagitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal paronychia
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal peritonitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal pharyngitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal retinitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal rhinitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal sepsis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal skin infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal tracheitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fungal urethritis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Funguria
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Fusarium infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Gastritis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis cryptococcal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal mucormycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Genital candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Genital infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Geotrichum infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Hepatic candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Hepatic infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Hepatosplenic candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Histoplasmosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Histoplasmosis cutaneous
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Histoplasmosis disseminated
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Keratitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Kerion
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Laryngeal cryptococcosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Laryngitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Lobomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Lower respiratory tract infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Lymphadenitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Malassezia infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mastitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis aspergillus
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis coccidioides
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis cryptococcal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis exserohilum
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis histoplasma
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Microsporum infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mucocutaneous candidiasis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mucormycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mycetoma mycotic
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mycotic corneal ulcer
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mycotic endophthalmitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Mycotoxicosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Myocarditis mycotic
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Nail candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Nasal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Necrotising fasciitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Neonatal candida infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Neoscytalidium infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Neurocryptococcosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Oesophageal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Onychomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Oral candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Oral fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Oro-pharyngeal aspergillosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Oropharyngeal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Oropharyngitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Osseous cryptococcosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Osteomyelitis blastomyces
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Osteomyelitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Otitis externa candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Otitis externa fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Overgrowth fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pancreatitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Paracoccidioides infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Penicillium infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis histoplasma
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Peritoneal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Phaeohyphomycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Phaeohyphomycotic brain abscess
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumocystis jirovecii infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumocystis jirovecii pneumonia
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia blastomyces
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia cryptococcal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Presumed ocular histoplasmosis syndrome
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis monilial
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pseudallescheria infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pseudallescheria sepsis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary mucormycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary paracoccidioidomycosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary sporotrichosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary trichosporonosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pyelonephritis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Pythium insidiosum infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory moniliasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory tract infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Retinitis histoplasma
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Rhinocerebral mucormycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Rhinosporidiosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Scedosporium infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Scopulariopsis infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Severe asthma with fungal sensitisation
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Sinusitis aspergillus
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Sinusitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Skin candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Splenic candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Splenic infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Sporotrichosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Stoma site candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Superinfection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Systemic candida
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Systemic mycosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea barbae
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea blanca
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea capitis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea cruris
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea faciei
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea imbricata
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea manuum
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea nigra
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea pedis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tinea versicolour
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tongue fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Tonsillitis fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Torulopsis infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Trichophytic granuloma
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Trichophytosis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Trichosporon infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Upper respiratory fungal infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Urogenital infection fungal
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginal candidiasis
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginal mycotic infection
Serious infections	Fungal infectious disorders (HLGT)		ASER eq 'Yes'	Wound infection fungal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Angiostrongylus infection
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Anisakiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Arthritis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Ascariasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Biliary tract infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Capillariasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Cestode infection
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Clonorchiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Cutaneous larva migrans
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Cystitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Dicrocoeliasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Diphyllobothriasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Dipylidiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Dirofilariasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Disseminated strongyloidiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Dracunculiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Echinococciasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Endocarditis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Enterobiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Enterocolitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Eye infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Fascioliasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Fasciolopsiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Filariasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Filariasis lymphatic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Gastritis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Genital infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Gnathostomiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Helminthic infection
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Hepatic echinococciasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Hepatic infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Heterophyiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Hookworm infection
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Hymenolepiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Lymphadenitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Meningoencephalitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Metagonimiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Myocarditis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Nematodiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Neurocysticercosis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Onchocerciasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Onchodermatitis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Opisthorchiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Oral helminthic infection
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Pancreatitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Paragonimiasis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Pericarditis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Peritonitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Pneumonia helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Pulmonary echinococciasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Renal echinococciasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Schistosomiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Schistosomiasis bladder
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Schistosomiasis cutaneous
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Schistosomiasis liver
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Skin infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Splenic infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Strongyloidiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Syngamiasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Taeniasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Thyroid echinococciasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Toxocariasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Trematode infection
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Trichiniasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Trichostrongyliasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Trichuriasis
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Tropical eosinophilia
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Upper respiratory tract infection helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Vulvovaginitis helminthic
Serious infections	Helminthic disorders (HLGT)		ASER eq 'Yes'	Wound infection helminthic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abdominal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abdominal hernia infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abdominal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abdominal sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abdominal wall abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abdominal wall infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abortion infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess intestinal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess jaw
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess limb
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess neck
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess of external auditory meatus
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess of eyelid
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess of salivary gland
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess oral
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess rupture
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess soft tissue
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Abscess sweat gland
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Acne pustular
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Activated PI3 kinase delta syndrome

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Acute endocarditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Acute sinusitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Adenoiditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Administration site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Administration site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Administration site joint infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Administration site pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Adrenal gland abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Adrenalitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Alveolar osteitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Amniotic cavity infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Amniotic infection syndrome of Blane
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Anal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Anal fistula infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Anal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Anal papillitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Anastomotic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Anorectal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Appendiceal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Appendicitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Appendicitis perforated
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Application site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Application site folliculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Application site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Application site joint infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Application site pustules
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Arteriovenous fistula site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Arteriovenous graft site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Arteriovenous graft site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Arteritis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Arthritis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Atypical pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bacteraemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bacterial toxaemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bacterial translocation
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bacteroides bacteraemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Balanoposthitis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bartholin's abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bartholinitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bezold abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Biliary abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Biliary sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Biliary tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Biloma infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bladder diverticulitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Blebitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Blister infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bone abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Brain abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Brain empyema
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Breast abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Breast discharge infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bronchitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Burn infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Bursitis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	CNS ventriculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Carbuncle
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cardiac infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cardiac valve abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cardiac valve vegetation
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Catheter site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Catheter site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Catheter site pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cavernous sinus thrombosis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cellulitis laryngeal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cellulitis pharyngeal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Central nervous system abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Central nervous system infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cerebral septic infarct
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cervicitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Chest wall abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cholangitis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cholecystitis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Chorioretinitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Chronic sinusitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Chronic tonsillitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Clitoris abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Coinfection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Colonic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Colostomy infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Complicated appendicitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Congenital infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Congenital pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Conjunctivitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Corneal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Corneal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cranial nerve infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cross infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Croup infectious
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Cystitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dacryocanaliculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dacryocystitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dental fistula
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dental gangrene
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dermatitis infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dermo-hypodermitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Device related bacteraemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Device related infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Device related sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Diabetic foot infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Diarrhoea infectious
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Diarrhoea infectious neonatal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Diverticulitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Diverticulitis intestinal haemorrhagic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Diverticulitis intestinal perforated
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Douglas' abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dural abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Dysentery
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ear infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ear lobe infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ecthyma
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eczema infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Embolic pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Emphysematous cholecystitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Emphysematous cystitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Emphysematous pyelonephritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Empyema
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Encephalitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Encephalitis brain stem
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Encephalitis lethargica
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Encephalomyelitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Endocarditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Endometritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Endometritis decidual
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Endophthalmitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Endotoxaemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Endotoxic shock
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Enteritis infectious
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Enterocolitis infectious
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ependymitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Epididymitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Epiglottitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Epiglottitis obstructive
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Erysipeloid
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Extradural abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eye abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eye infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eye infection intraocular

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eyelid boil
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eyelid folliculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Eyelid infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Fallopian tube abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Fascial infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Febrile infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Focal peritonitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Fournier's gangrene
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Fracture infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Fungaemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Funisitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gallbladder abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gallbladder empyema
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gastric infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gastroenteritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gastrointestinal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Genital abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Genital infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Genital infection female
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Genital infection male
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Genital ulcer syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Genitourinary tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gingival abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gingivitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Gradenigo's syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Graft infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Groin abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Groin infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Haematoma infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Haemorrhagic pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Haemorrhoid infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hepatic cyst infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hepatic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hepatitis post transfusion
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hepatobiliary infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hepatosplenic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hordeolum
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hydrocele male infected
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Hypopyon
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Impetigo
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Implant site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Implant site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Implant site pustules
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Incision site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Induced abortion infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infantile septic granulomatosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected bite
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected bunion
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected cyst
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected dermal cyst
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected fistula
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected gouty tophus
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected large intestinal ulcer
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected lymphocele
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected naevus
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected neoplasm
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected seroma
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected skin ulcer
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected urinoma
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected varicose vein
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infected vasculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infection in an immunocompromised host
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infection masked
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infection parasitic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infection reactivation
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infection susceptibility increased
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infectious crystalline keratopathy
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infectious iridocyclitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infectious pleural effusion
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infectious thyroiditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective aneurysm
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective aortitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective chondritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective corneal ulcer
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective episcleritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective exacerbation of bronchiectasis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective exacerbation of chronic obstructive airways disease
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective glossitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective iritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective keratitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective mesenteric panniculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective myositis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective pericardial effusion
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective periostitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective pulmonary exacerbation of cystic fibrosis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective scleritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective spondylitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective tenosynovitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective thrombosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infective uveitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infusion site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infusion site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infusion site joint infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Infusion site pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Injection site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Injection site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Injection site joint infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Injection site pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Instillation site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Instillation site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Instillation site pustules
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Intervertebral discitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Intestinal fistula infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Intestinal sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Intracranial infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Intrauterine infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Joint abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Keratouveitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Kidney infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Labyrinthitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lacrimal gland abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Large intestine infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Laryngitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Laryngopharyngitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Laryngotracheitis obstructive
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lip infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Liver abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Localised infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lochial infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lower respiratory tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ludwig angina
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lung abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lymph gland infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lymph node abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Lymphangitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mastitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mastitis postpartum
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mastoid abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mastoid empyema
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mastoiditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mediastinal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mediastinitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Medical device site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Medical device site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Medical device site joint infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Medical device site pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Meningitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Meningitis aseptic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Meningitis neonatal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mesenteric abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Miliary pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mononucleosis syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Mucosal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Muscle abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Myelitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Myocardiac abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Myocarditis infectious
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Myocarditis septic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Myometritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Myringitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Nail bed infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Nail infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Nasal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Nasal vestibulitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Nasopharyngitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Necrotising fasciitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Necrotising soft tissue infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neonatal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neonatal infective mastitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neonatal pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neovaginal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neurological infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neutropenic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Neutropenic sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Nipple infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Obstetric infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Oculoglandular syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Oesophageal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Oesophageal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Omphalitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Oophoritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ophthalmia neonatorum
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Opportunistic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Oral infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Oral pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Orbital infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Orchitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Osteomyelitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Osteomyelitis acute
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Osteomyelitis chronic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Otitis externa

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Otitis media
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Otitis media acute
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Otitis media chronic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Otosalpingitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ovarian abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Overgrowth of nonsusceptible organisms
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pancreas infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pancreatic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Panencephalitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Papillon-Lefevre syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Paracancerous pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parametric abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parametritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Paranasal mucopyocoele
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Paranasal sinus abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parapharyngeal space infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parasite allergy
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parasitic encephalitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parasitic gastroenteritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parasitic oesophagitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parasitic pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Paraspinal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parathyroid gland abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parotid abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Parotitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pathogen resistance
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pelvic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pelvic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pelvic inflammatory disease
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pelvic sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Penile abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Penile infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Peri-implantitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pericarditis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pericoronitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perihepatic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perihepatitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perineal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perineal cellulitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perineal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perinephric abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Periodontal destruction
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Periodontitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Periorbital abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Periorbital infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Peripheral nerve infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Perirectal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Peritoneal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Peritonitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Peritonsillar abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Peritonsillitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Periumbilical abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Petrositis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pharyngeal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pharyngeal pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pharyngitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pharyngolaryngeal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pharyngotonsillitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Phlebitis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pilonidal cyst
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pilonidal cyst congenital
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pitted keratolysis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pleural infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pneumonia necrotising
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Portal pyaemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Post abortion infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Post procedural infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Post procedural pneumonia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Post procedural sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Postoperative abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Postoperative wound infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Postpartum sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Prostate infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Prostatic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pseudoaneurysm infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Psoas abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Puerperal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Puerperal pyrexia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pulmonary sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pulpitis dental
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Puncture site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Puncture site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Purulence
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Purulent discharge
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Purulent pericarditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Purulent synovitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyelitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyelocystitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyelonephritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyelonephritis acute

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyelonephritis chronic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyloric abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyoderma
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyometra
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyonephrosis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyopneumothorax
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyospermia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Pyuria
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Rash pustular
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Rectal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Rectovaginal septum abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Recurrent pyogenic cholangitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Recurrent subareolar breast abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Renal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Renal cyst infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Renal graft infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Respiratory tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Retinitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Retroperitoneal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Retroperitoneal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Retroperitonitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Rhinitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Rhinolaryngitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Rhinotracheitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Root canal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Salpingitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Salpingo-oophoritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Scrotal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Scrotal cellulitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Scrotal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sebaceous gland infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Seminal vesicle abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Seminal vesicular infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sepsis neonatal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sepsis syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic coagulopathy
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic embolus
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic encephalopathy
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic necrosis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic phlebitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic pulmonary embolism
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic rash
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic shock
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Septic vasculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Shunt infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sialoadenitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sinobronchitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sinusitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Skin graft infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Skin infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Soft tissue infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Southern tick-associated rash illness
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Spermatic cord funiculitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Spinal cord abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Spinal cord infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Spinal empyema
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Splenic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Splenic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sputum purulent
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sternitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Stitch abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Stoma site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Stoma site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subacute endocarditis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subarachnoid abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subcutaneous abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subdiaphragmatic abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subdural abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subgaleal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subglottic laryngitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Subperiosteal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Superinfection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Sweat gland infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Systemic infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	TORCH infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Testicular abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Thrombophlebitis septic
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Thymus abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Thyroglossal cyst infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Thyroid gland abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tick-borne fever
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tongue abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tonsillitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tooth abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tooth infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tornwaldt bursitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Toxic shock syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tracheal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tracheitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tracheitis obstructive
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tracheobronchitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tracheostomy infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Transplant abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tropical infectious disease
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tropical ulcer
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Tubo-ovarian abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Umbilical sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Upper aerodigestive tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Upper respiratory tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urachal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ureter abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Ureteritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urethral abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urethral carbuncle
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urethral discharge syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urethral stricture post infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urethritis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urinary bladder abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urinary meatitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urinary tract abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urinary tract infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urinary tract infection neonatal
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Urosepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Uterine abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Uterine infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaccination site abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaccination site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaccination site joint infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaccination site pustule
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaccine breakthrough infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaginal abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vaginal infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vascular access site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vascular device infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vascular graft infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vessel puncture site infection
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vestibulitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Viraemia
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Virologic failure
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Visceral larva migrans
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vitreous abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vitritis infective
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vulval abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vulvitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Vulvovaginitis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Wound abscess
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Wound infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Wound sepsis
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Young's syndrome
Serious infections	Infections - pathogen unspecified (HLGT)		ASER eq 'Yes'	Zoonosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Adrenal gland tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Atypical mycobacterial infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Atypical mycobacterial lower respiratory tract infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Atypical mycobacterial lymphadenitis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Atypical mycobacterial pneumonia
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Atypical mycobacterium pericarditis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bone tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Borderline leprosy
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Bovine tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Choroid tubercles
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Congenital tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Conjunctivitis tuberculous
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated Bacillus Calmette-Guerin infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated mycobacterium avium complex infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Ear tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Epididymitis tuberculous
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Erythema induratum
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Extrapulmonary tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Female genital tract tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Immune reconstitution inflammatory syndrome associated tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Indeterminate leprosy
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Intestinal tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Joint tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Latent tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lepromatous leprosy
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Leprosy
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lupus vulgaris
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Lymph node tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Male genital tract tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mammary tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis tuberculous
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterial infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterial peritonitis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium abscessus infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium avium complex immune restoration disease
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium avium complex infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium chelonae infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium fortuitum infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium haemophilum infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium kansasii infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium marinum infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Mycobacterium ulcerans infection
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Oesophageal tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Oral tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis tuberculous
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Peritoneal tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Prostatitis tuberculous
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary tuberculoma
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Pulmonary tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Renal tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Salpingitis tuberculous
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Silicotuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Spleen tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Superinfection mycobacterial
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Thyroid tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculoid leprosy
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculoma of central nervous system
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis bladder
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis gastrointestinal
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis liver
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis of central nervous system
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis of eye
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis of genitourinary system
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis of intrathoracic lymph nodes
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis of peripheral lymph nodes
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculosis ureter
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculous endometritis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculous laryngitis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculous pleurisy
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Tuberculous tenosynovitis
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Type 1 lepra reaction
Serious infections	Mycobacterial infectious disorders (HLGT)		ASER eq 'Yes'	Type 2 lepra reaction
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Cervicitis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Epididymitis ureaplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Mycoplasma genitalium infection
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Mycoplasma infection
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Mycoplasmal postabortal fever
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Mycoplasmal postpartum fever
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Pelvic inflammatory disease mycoplasmal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Pharyngitis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Pyelonephritis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Tracheobronchitis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Ureaplasma cervicitis
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Ureaplasma infection
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Ureaplasmal vulvovaginitis
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Urethritis mycoplasmal
Serious infections	Mycoplasmal infectious disorders (HLGT)		ASER eq 'Yes'	Urethritis ureaplasmal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Acanthamoeba infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Acanthamoeba keratitis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	African trypanosomiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	American trypanosomiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Amoebiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Amoebic brain abscess
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Amoebic colitis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Amoebic dysentery
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Amoebic lung abscess
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Amoebic skin ulcer
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Babesiosis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Balamuthia infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Balantidiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Biliary tract infection cryptosporidial
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Blackwater fever
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Blastocystis infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Cerebral malaria
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Cerebral toxoplasmosis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Cervicitis trichomonal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Chagas' cardiomyopathy
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Chagoma
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Congenital malaria
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Congenital toxoplasmosis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Cryptosporidiosis infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Cutaneous leishmaniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Cyclosporidium infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Dientamoeba infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated leishmaniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated toxoplasmosis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis protozoal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection toxoplasmal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis cryptosporidial
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal protozoal infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Giardiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Hepatic amoebiasis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis toxoplasmal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Infection protozoal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Isosporiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Leishmaniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Malaria
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Malaria recrudescence
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Malaria relapse
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Malarial myocarditis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis toxoplasmal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis trypanosomal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Meningoencephalitis amoebic
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Microsporidia infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Mucocutaneous leishmaniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Myocarditis toxoplasmal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Naegleria infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Pericarditis amoebic
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Plasmodium falciparum infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Plasmodium knowlesi infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Plasmodium malariae infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Plasmodium ovale infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Plasmodium vivax infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia toxoplasmal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Prostatitis trichomonal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Protothecosis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Protozoal corneal ulcer
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Romana's sign
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Sarcocystis infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Toxoplasmosis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Trichomoniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Trichomoniasis intestinal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Trypanosomiasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Urethritis trichomonal
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Urogenital trichomoniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Visceral leishmaniasis
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Vorticella infection
Serious infections	Protozoal infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginitis trichomonal
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Boutonneuse fever
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Coxiella infection
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis rickettsial
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis Q fever
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Epidemic typhus
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Human anaplasmosis
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Human ehrlichiosis
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Japanese spotted fever
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Murine typhus
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	North Asian tick typhus

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Q fever
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Queensland tick typhus
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Recrudescent typhus
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Rickettsialpox
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Rickettsioses not tick borne
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Rickettsiosis
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Rocky mountain spotted fever
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Scrub typhus
Serious infections	Rickettsial infectious disorders (HLGT)		ASER eq 'Yes'	Typhus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	AIDS cholangiopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	AIDS dysmorphic syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	AIDS related complex
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	AIDS related complication
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	AIDS retinopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Acquired immunodeficiency syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Acute HIV infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Acute haemorrhagic conjunctivitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Acute hepatitis B
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Acute hepatitis C
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenoviral conjunctivitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenoviral encephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenoviral haemorrhagic cystitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenoviral hepatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenoviral meningitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenoviral upper respiratory infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenovirus encephalomyeloradiculitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Adenovirus reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Alongshan virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Alphaviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Anogenital warts
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Anorectal human papilloma virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Arboviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Arenaviral haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Argentine haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Arthritis rubella
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Arthritis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Asymptomatic COVID-19
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Asymptomatic HIV infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Asymptomatic viral hepatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Avian influenza
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	BK virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Biliary tract infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Blepharal papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Bolivian haemorrhagic fever

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Boston exanthema
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Bovine pustular stomatitis virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Bronchiolitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Bronchitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Bulbar poliomyelitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Buschke-Lowenstein's tumour
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	COVID-19
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	COVID-19 pneumonia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	CSF HIV escape syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cataract congenital
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Central nervous system enteroviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Central nervous system viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cervicitis human papilloma virus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cervix warts
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Chikungunya virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Choriomeningitis lymphocytic
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Chronic active Epstein-Barr virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Chronic hepatitis B
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Chronic hepatitis C
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Colitis herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Colorado tick fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital COVID-19
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital Ebola virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital HIV infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital Zika syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital condyloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital cytomegalovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital dengue disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital hepatitis B infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital hepatitis C infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital herpes simplex infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital rubella infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital rubella syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital varicella infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congenital viral hepatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Congo-Crimean haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Conjunctivitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coronavirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cow pox
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie bronchitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie carditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie endocarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie myocarditis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie pericarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie viral disease of the newborn
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Coxsackie viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Creutzfeldt-Jakob disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cystitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus chorioretinitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus colitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus duodenitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus enteritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus enterocolitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus gastritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus gastroenteritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus gastrointestinal infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus gastrointestinal ulcer
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus hepatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus infection reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus mononucleosis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus mucocutaneous ulcer
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus myelomeningoradiculitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus myocarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus nephritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus oesophagitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus pancreatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus pericarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus urinary tract infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Cytomegalovirus viraemia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Dengue fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Dengue haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated cytomegaloviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated neonatal herpes simplex
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated varicella
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated varicella zoster vaccine virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Disseminated varicella zoster virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Ear infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Ebola Reston virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Ebola disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Echo virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Eczema Coxsackium
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Eczema herpeticum
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Eczema vaccinatum
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis Japanese B

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis australia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis california
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis cytomegalovirus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis eastern equine
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis enteroviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis influenzal
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis venezuelan equine
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalitis western equine
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Encephalomyelitis rubella
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	End stage AIDS
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Endocarditis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Enterocolitis AIDS
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Enterocolitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Enterovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Enterovirus myocarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epidemic pleurodynia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epidemic polyarthritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epidermodysplasia verruciformis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epididymitis mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epstein Barr virus positive mucocutaneous ulcer
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epstein-Barr viraemia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epstein-Barr virus associated lymphoma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epstein-Barr virus associated lymphoproliferative disorder
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epstein-Barr virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Epstein-Barr virus infection reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Eruptive pseudoangiomatosis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Erythema infectiosum
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Exanthema subitum
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Eye infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Fatal familial insomnia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Filovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Flavivirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Focal epithelial hyperplasia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Foot and mouth disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastritis herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastritis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis adenovirus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis astroviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis caliciviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis enteroviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis norovirus

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis rotavirus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis sapovirus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastroenteritis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gastrointestinal viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Generalised vaccinia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Genital herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Genital herpes simplex
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Genital herpes zoster
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Genital infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gerstmann Straussler Scheinker syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Gianotti-Crosti syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	H1N1 influenza
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	H2N2 influenza
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	H3N2 influenza
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HCoV-229E infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HCoV-HKU1 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HCoV-NL63 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HCoV-OC43 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV associated nephropathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV cardiomyopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV enteropathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group I
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group II
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group III
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group IV subgroup A
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group IV subgroup B
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group IV subgroup C1
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group IV subgroup C2
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group IV subgroup D
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC Group IV subgroup E
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC category A
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC category B
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC category C
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection CDC group IV
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection WHO clinical stage I
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection WHO clinical stage II
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection WHO clinical stage III
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV infection WHO clinical stage IV
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV lipodystrophy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV meningoencephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV peripheral neuropathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV viraemia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV wasting syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV-2 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	HIV-associated neurocognitive disorder

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Haemorrhagic fever with renal syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Haemorrhagic varicella syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hand-foot-and-mouth disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hantaviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hantavirus pulmonary infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Heartland virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis A
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis B
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis B reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis C
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis D
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis E
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis F
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis G
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis H
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis infectious mononucleosis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis non-A non-B
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis non-A non-B non-C
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Hepatitis virus-associated nephropathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpangina
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes dermatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes oesophagitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes ophthalmic
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes pharyngitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes sepsis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex bronchitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex cervicitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex colitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex encephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex gastritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex hepatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex meningitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex meningoencephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex meningomyelitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex necrotising retinopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex oesophagitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex otitis externa
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex pharyngitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex pneumonia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex sepsis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex viraemia

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex virus conjunctivitis neonatal
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes simplex visceral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster cutaneous disseminated
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster infection neurological
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster meningitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster meningoencephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster meningomyelitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster meningoradiculitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster necrotising retinopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster oticus
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster pharyngitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpes zoster reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Herpetic radiculopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human T-cell lymphocytic virus type II infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human T-cell lymphotropic virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human T-cell lymphotropic virus type I infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human bocavirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human herpesvirus 6 encephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human herpesvirus 6 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human herpesvirus 6 infection reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human herpesvirus 7 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human herpesvirus 8 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Human polyomavirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Infectious mononucleosis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Influenza
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	JC virus granule cell neuronopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	JC virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Kaposi sarcoma inflammatory cytokine syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Kaposi's sarcoma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Kaposi's sarcoma AIDS related
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Keratitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Keratoconjunctivitis measles
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Kuru
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Kyasanur Forest disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Laryngeal papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Laryngitis viral

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Lassa fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Louping ill
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Lower respiratory tract herpes infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Lower respiratory tract infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Lujo haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Lymphadenitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Lymphoma AIDS related
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Marburg disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Measles
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Measles meningitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Measles post vaccine
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis coxsackie viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis echo viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis enteroviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningoencephalitis herpes simplex neonatal
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningoencephalitis herpetic
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningoencephalitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Meningomyelitis herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Merkel cell polyomavirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Metapneumovirus bronchiolitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Metapneumovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Metapneumovirus pneumonia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Middle East respiratory syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Milker's nodules
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Molluscum contagiosum
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Monkeypox
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Mumps deafness
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Murray Valley encephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Nail bed infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Nasal herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Necrotising herpetic retinopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Neonatal mucocutaneous herpes simplex
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Newcastle disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Nipah virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Norovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	O'nyong-nyong fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Omsk haemorrhagic fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Ophthalmic herpes simplex
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Ophthalmic herpes zoster
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Oral hairy leukoplakia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Oral herpes

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Oral papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Oral viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Orbivirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Orchitis mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Orf
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Oropouche fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Orthopox virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Osteomyelitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Otitis externa viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media post measles
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Otitis media viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pancreatitis mumps
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pancreatitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Papilloma viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Papular pruritic eruption of HIV
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parainfluenzae viral bronchitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parainfluenzae viral laryngotracheobronchitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parainfluenzae virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parapox virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Paravaccinia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parechovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parvovirus B19 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parvovirus B19 infection reactivation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Parvovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Penile wart
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Perinatal HBV infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Perinatal HIV infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Peritonitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Persistent generalised lymphadenopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pharyngoconjunctival fever of children
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Phlebotomus fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Picornavirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pleurisy viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia adenoviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia cytomegaloviral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia herpes viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia influenzal
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia measles
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia parainfluenzae viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia respiratory syncytial viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pneumonia viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pogosta disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Polioencephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Poliomyelitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Polyneuropathy mumps

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Polyomavirus viraemia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Polyomavirus-associated nephropathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Post measles blindness
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Post transplant lymphoproliferative disorder
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Post vaccination autoinoculation
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Post viral fatigue syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Post-acute COVID-19 syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Prion disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Proctitis herpes
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Progressive multifocal leukoencephalopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Progressive vaccinia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Pyelonephritis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rabies
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Reoviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory syncytial virus bronchiolitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory syncytial virus bronchitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory syncytial virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Respiratory tract infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Retinitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Retroviral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Retroviral rebound syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rhinovirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rift Valley fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rocio virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rotavirus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rubella
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rubella in pregnancy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Rubella infection neurological
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	SARS-CoV-2 sepsis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	SARS-CoV-2 viraemia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Severe acute respiratory syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Severe fever with thrombocytopenia syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Sinonasal papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Skin papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Slow virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Smallpox
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Snowshoe hare virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Splenic infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	St. Louis encephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Superinfection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Suspected COVID-19

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Sweating fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Systemic viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	T-cell lymphoma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	T-cell type acute leukaemia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Tick-borne viral encephalitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Tracheal papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Tracheobronchitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Tropical spastic paresis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Urethral papilloma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Urinary tract infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vaccine associated paralytic poliomyelitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vaccine derived SARS-CoV-2 infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vaccinia virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vaginitis viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Variant Creutzfeldt-Jakob disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella keratitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella post vaccine
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella zoster gastritis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella zoster oesophagitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella zoster pneumonia
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella zoster sepsis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Varicella zoster virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vestibular neuronitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral acanthoma
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral cardiomyopathy
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral corneal ulcer
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral diarrhoea
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral epiglottitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral haemorrhagic cystitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral keratouveitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral labyrinthitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral mastitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral myelitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral myocarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral myositis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral oesophagitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral parotitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral pericarditis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral pharyngitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral rash
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral rhinitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral sepsis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral sinusitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral skin infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral tonsillitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral tracheitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral upper respiratory tract infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral uveitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Viral vasculitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginal human papilloma virus infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Vulvovaginal warts
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	West Nile viral infection
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Withdrawal hepatitis
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Wound infection viral
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	X-linked lymphoproliferative syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Yellow fever
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Yellow fever vaccine-associated neurotropic disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Yellow fever vaccine-associated viscerotropic disease
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Zika virus associated Guillain Barre syndrome
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Zika virus associated birth defect
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Zika virus associated microencephaly
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Zika virus associated ocular birth defect
Serious infections	Viral infectious disorders (HLGT)		ASER eq 'Yes'	Zika virus infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Acute encephalitis with refractory, repetitive partial seizures
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Acute motor axonal neuropathy
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Acute motor-sensory axonal neuropathy
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Air-borne transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Arthritis reactive
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Arthropod-borne disease
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Axonal and demyelinating polyneuropathy
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Bacterial disease carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Bickerstaff's encephalitis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Bullous oedema of the bladder
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Chronic gastritis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Chronic hepatitis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Ciliary ganglionitis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Community acquired infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Cutaneous malacoplakia
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Degenerative multivalvular disease
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Diphtheria carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Direct infection transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Encephalitis post immunisation
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Encephalitis post varicella

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Endocarditis rheumatic
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Erythema marginatum
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Faecal-oral transmission of infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Febrile infection-related epilepsy syndrome
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Follicular cystitis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Food poisoning
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Fungal disease carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Granulomatous lymphadenitis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Guillain-Barre syndrome
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	HIV carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	HTLV-1 carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Hepatitis chronic active
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Hepatitis chronic persistent
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Hepatitis fulminant
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Human immunodeficiency virus transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Iatrogenic infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Indirect infection transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Infantile acropustulosis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Infection transmission via personal contact
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Infection via vaccinee
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Infectious disease carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Kawasaki's disease
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Keratoderma blenorrhagica
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Malacoplakia
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Malacoplakia gastrointestinal
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Malacoplakia of bone
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Malacoplakia vesicae
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Multisystem inflammatory syndrome in children
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Mycobacterial disease carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Myocarditis post infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Nosocomial infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Pericarditis rheumatic
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Poncet's disease
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Post herpetic neuralgia
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Post infection glomerulonephritis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Post polio syndrome
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Post streptococcal glomerulonephritis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Primary transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Progressive massive fibrosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Psorospermiasis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Reye's syndrome
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Rheumatic fever
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Rheumatic heart disease
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Roseola
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	SARS-CoV-2 carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	SJS-TEN overlap
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Scleroedema
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Secondary amyloidosis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Secondary transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Sexual transmission of infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Sexually transmitted disease
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Sexually transmitted disease carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Sporadic infantile bilateral striatal necrosis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Stevens-Johnson syndrome
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Subacute inflammatory demyelinating polyneuropathy
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Subacute sclerosing panencephalitis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Suspected transmission of an infectious agent via product
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Sydenham's chorea
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Thyroiditis subacute
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Tick paralysis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Toxic epidermal necrolysis
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Transmission of an infectious agent via product
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Transmission of an infectious agent via transplant
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Typhoid carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Vaccine bacteria shedding
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Vaccine virus shedding
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Vector-borne transmission of infection
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Vertical infection transmission
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Viral disease carrier
Severe infections	Ancillary infectious topics (HLGT)		ATOXGRN ge 3	Viral hepatitis carrier
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Abdominal hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Abscess bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Achromobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Acid fast bacilli infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Acinetobacter bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Acinetobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Acinetobacter sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Acrodermatitis chronica atrophicans
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Actinomycosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Actinomycotic abdominal infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Actinomycotic pulmonary infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Actinomycotic sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Actinomycotic skin infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Adenopathy syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Administration site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Aerococcus urinae infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Aeromonas infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Alcaligenes infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Alopecia syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Alpha haemolytic streptococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Angina gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Anicteric leptospirosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Anorectal cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Anorectal infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Anthrax
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Anthrax sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Antibiotic associated colitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Aortic aneurysm syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Aortitis salmonella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Aortitis syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Application site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Arteriosclerotic gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Arthritis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Arthritis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Arthritis salmonella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Asymptomatic bacteriuria
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacillary angiomatosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacillus bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacillus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterascites
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial abdominal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial abscess central nervous system
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial allergy
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial blepharitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial colitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial dacryocystitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial diarrhoea
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial endophthalmitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial food poisoning
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial gingivitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial iritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial labyrinthitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial myositis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial parotitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial pericarditis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial prostatitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial pyelonephritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial rhinitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial salpingitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial tracheitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial ureteritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial urethritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial vaginosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacterial vulvovaginitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacteriuria
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacteriuria in pregnancy
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bacteroides infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bartonellosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Beta haemolytic streptococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bifidobacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Biliary tract infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bordetella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Borrelia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Botryomycosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Botulism
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Brachyspira infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Brazilian purpuric fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Breast cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Brevibacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis moraxella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis pneumococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Brucella sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Brucellosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bubonic plague
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bullous erysipelas
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bullous impetigo
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Burkholderia cepacia complex infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Burkholderia cepacia complex sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Burkholderia gladioli infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Burkholderia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Burkholderia mallei infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Burkholderia pseudomallei infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bursitis infective staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Campylobacter colitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Campylobacter gastroenteritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Campylobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Campylobacter sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Campylobacter urinary tract infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Capnocytophaga infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Capnocytophaga sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cardiovascular syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cat scratch disease
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Catheter site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis enterococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis of male external genital organ
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis orbital
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis pasteurella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cellulitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cerebral aneurysm ruptured syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cervicitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cervicitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Chancroid
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cholera
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Citrobacter bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Citrobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Citrobacter sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Clostridial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Clostridial sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Clostridium bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Clostridium colitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Clostridium difficile colitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Clostridium difficile infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Colon gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Condyloma latum
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Congenital syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Congenital syphilitic encephalitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Congenital syphilitic meningitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Congenital syphilitic osteochondritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Conjunctivitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Conjunctivitis gonococcal neonatal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Corynebacterium bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Corynebacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Corynebacterium sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cronobacter bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cronobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cronobacter necrotising enterocolitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous anthrax
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous listeriosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous nocardiosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cystitis bacterial

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cystitis escherichia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cystitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cystitis klebsiella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cystitis pseudomonal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Delftia acidovorans infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Diabetic gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Diaphragmatic hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Diphtheria
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Ear infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Ear infection staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Eczema impetiginous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Empedobacter brevis infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis meningococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endemic syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis enterococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis meningococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis pseudomonal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endometritis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Endometritis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enteritis necroticans
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterobacter bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterobacter pneumonia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterobacter sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterobacter tracheobronchitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterococcal bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterococcal gastroenteritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterococcal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Enterocolitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Epididymo-orchitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Epiglottitis haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Erysipelas
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Erysipelothrix infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Erysipelothrix sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Erythema migrans
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Erythrasma
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia peritonitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia pyelonephritis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia urinary tract infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Escherichia vaginitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Eubacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	External ear cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Femoral hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Flavobacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Folliculitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Furuncle
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Fusobacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gangrene neonatal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gangrenous balanitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gardnerella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gas gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastric ulcer helicobacter
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastritis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis Escherichia coli
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis aerobacter
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis aeromonas
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis bacillus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis clostridial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis listeria
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis paracolon bacillus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis proteus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis pseudomonas
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis salmonella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis shigella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis vibrio
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis yersinia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal anthrax
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal bacterial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal bacterial overgrowth
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Genital infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Genitourinary tract gonococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Giant fornix syndrome
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gonococcal heart disease
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gonococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gonococcal pelvic inflammatory disease

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Gonorrhoea
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Granulicatella bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Granulicatella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Granuloma inguinale
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Group B streptococcus neonatal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Haemophilus bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Haemophilus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Haemophilus sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Helicobacter duodenal ulcer
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Helicobacter duodenitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Helicobacter gastritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Helicobacter infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Helicobacter sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Hepatic gas gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Hepatic infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Ileal gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Implant site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Incision site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Incisional hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Infusion site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Inguinal hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Injection site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Intestinal gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Janeway lesion
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Jejunal gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Keratitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Keratosis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Klebsiella bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Klebsiella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Klebsiella sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lacrimal sac cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lactobacillus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Laryngitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Latent syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Legionella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lemierre syndrome
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Leptospira sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Leptospirosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Leptotrichia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Leuconostoc infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lineal gingival erythema
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Listeraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Listeria encephalitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Listeria sepsis

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Listeriosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lower respiratory tract infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lyme carditis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lyme disease
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lymphadenitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Malignant syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mastitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Medical device site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis Escherichia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis borrelia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis cronobacter
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis enterococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis leptospiral
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis listeria
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis meningococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis pneumococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis salmonella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningococcal bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningococcal carditis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningococcal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningoencephalitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Methylobacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Micrococcal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Micrococcus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Moraxella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Morganella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Myocarditis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Myocarditis meningococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Myocarditis syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Nail bed infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Necrobacillosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Necrotising fasciitis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Necrotising fasciitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Necrotising ulcerative gingivostomatitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Necrotising ulcerative periodontitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Neisseria infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Nephritis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Neuroborreliosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Neurosyphilis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Nocardia sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Nocardiosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Oesophagitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Optic neuritis meningococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Oral bacterial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Oropharyngeal gonococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Osler's nodes
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Osteomyelitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Osteomyelitis salmonella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Otitis externa bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media moraxella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media pneumococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Ovarian bacterial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Overgrowth bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pancreatitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pantoea agglomerans infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Paratyphoid fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Paronychia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Parvimonas infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Parvimonas micra infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pasteurella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Penile gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peptic ulcer helicobacter
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peptostreptococcus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Perianal streptococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis meningococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Perichondritis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Perihepatitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Periorbital cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Periporitis staphylogenes
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peritonitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peritonitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peritonitis pneumococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peritonitis syphilitic
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pertussis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peruvian wart
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pharyngitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pharyngitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pinta
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Plague
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Plague sepsis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pleural infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumococcal bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumococcal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia acinetobacter
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia anthrax
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia bordetella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia escherichia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia klebsiella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia legionella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia moraxella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia pneumococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia proteus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia pseudomonal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia salmonella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia serratia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia tularaemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonic plague
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pontiac fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Porphyromonas infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Post procedural cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Post treatment Lyme disease syndrome
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Primary syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Propionibacterium infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Prostatitis Escherichia coli
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Prostatitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Proteus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Providencia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Providencia urinary tract infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomembranous colitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonal bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonal skin infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonas aeruginosa meningitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonas bronchitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonas infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pseudomonas peritonitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary nocardiosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Puncture site cellulitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Purple urine bag syndrome
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pyoderma streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pyomyositis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Raoultella ornithinolytica infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Relapsing fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Renal syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory tract infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Rhinoscleroma
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Rhodococcus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Salmonella bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Salmonella sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Salmonellosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Salpingitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Scarlet fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Scrotal gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Secondary syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Seminal vesiculitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Sepsis pasteurella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Septic arthritis haemophilus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Septic arthritis neisserial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Septic arthritis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Septic arthritis streptobacillus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Septic arthritis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Serratia bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Serratia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Serratia sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Severe invasive streptococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Shewanella algae bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Shigella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Shigella sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Sinusitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Skin bacterial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Small intestine gangrene
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Sphingomonas paucimobilis bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Sphingomonas paucimobilis infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Spirillary fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Spirochaetal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Splenic infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal abscess
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal blepharitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal impetigo
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal mediastinitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal osteomyelitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal parotitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal pharyngitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal scalded skin syndrome
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal skin infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Staphylococcal toxaemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Stenotrophomonas bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Stenotrophomonas infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Stenotrophomonas sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Stoma site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Stomatococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptobacillary fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptobacillus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal abscess
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal bronchitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal endocarditis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal impetigo
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Streptococcal urinary tract infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Superinfection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Sycosis barbae
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Syphilis anal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Syphilis genital
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Syphilis musculoskeletal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Syphilitic endocarditis of heart valve
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Systemic bacterial infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Systemic bartonellosis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tertiary syphilis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tetanus
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tetanus neonatorum
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tonsillitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tonsillitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Toxic shock syndrome staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Toxic shock syndrome streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tracheobronchitis bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Trench fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculous abscess central nervous system
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tularaemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Typhoid fever
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Umbilical hernia gangrenous
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Upper respiratory tract infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Urethritis gonococcal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract infection enterococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract infection pseudomonal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract infection staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Urogenital infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vaccination site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vaginal cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vaginitis gardnerella
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Veillonella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vessel puncture site cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vibrio vulnificus infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vulval cellulitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginitis gonococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginitis staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginitis streptococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Waterhouse-Friderichsen syndrome
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Weil's disease
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Weissella infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Whipple's disease
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Wound infection bacterial
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Wound infection pseudomonas
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Wound infection staphylococcal
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yaws
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yaws of bone
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yaws of skin
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yersinia bacteraemia
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yersinia infection
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yersinia meningitis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Yersinia sepsis
Severe infections	Bacterial infectious disorders (HLGT)		ATOXGRN ge 3	Zoonotic bacterial infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Anal chlamydia infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Chlamydial cervicitis
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Chlamydial infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Chlamydial pelvic inflammatory disease
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Conjunctivitis chlamydial
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection chlamydial
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Genitourinary chlamydia infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Gynaecological chlamydia infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Inclusion conjunctivitis
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Inclusion conjunctivitis neonatal
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Lymphogranuloma venereum
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Peritoneal chlamydia infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Pharyngeal chlamydia infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia chlamydial
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis chlamydial
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Psittacosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory tract chlamydial infection
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Trachoma
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Urethritis chlamydial
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Vaginitis chlamydial
Severe infections	Chlamydial infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginitis chlamydial
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Acariasis
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Acarodermatitis
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Arthropod infestation
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Bed bug infestation
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Demodicidosis
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Flea infestation
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Hirudiniasis
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Infestation
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Lice infestation
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Myiasis
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Trombidiasis
Severe infections	Ectoparasitic disorders (HLGT)		ATOXGRN ge 3	Tungiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Abscess fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Acute pulmonary histoplasmosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Allergic bronchopulmonary mycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Allescheriosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Alternaria infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Anal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Anal fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Anal tinea
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Arthritis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Aspergilloma
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Aspergillosis oral
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Aspergillus infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Aureobasidium pullulans infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Balanitis candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Biliary tract infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Black piedra
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Bladder candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Blastomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Body tinea
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Bronchopulmonary aspergillosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Bronchopulmonary aspergillosis allergic
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida cervicitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida endophthalmitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida nappy rash
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida osteomyelitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida pneumonia
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida retinitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida sepsis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candida urethritis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Candidiasis of trachea
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Central nervous system fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cerebral aspergillosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cerebral candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cerebral fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Chromoblastomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Chronic pulmonary histoplasmosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Coccidioides encephalitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Coccidioidomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Conjunctivitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cryptococcal cutaneous infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cryptococcal fungaemia
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cryptococcal meningoencephalitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cryptococcosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous blastomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous coccidioidomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous mucormycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous sporotrichosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Denture stomatitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Dermatophytosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Dermatophytosis of nail
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated aspergillosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated blastomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated coccidioidomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated cryptococcosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated mucormycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated paracoccidioidomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated sporotrichosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated trichosporonosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Ear infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis histoplasma
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Enterocolitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Epididymitis blastomyces
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Exserohilum infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal abscess central nervous system
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal balanitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal cystitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal endocarditis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal labyrinthitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal oesophagitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal paronychia
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal peritonitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal pharyngitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal retinitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal rhinitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal sepsis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal skin infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal tracheitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fungal urethritis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Funguria
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Fusarium infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Gastritis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis cryptococcal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal mucormycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Genital candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Genital infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Geotrichum infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Hepatic candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Hepatic infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Hepatosplenic candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Histoplasmosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Histoplasmosis cutaneous
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Histoplasmosis disseminated
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Keratitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Kerion
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Laryngeal cryptococcosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Laryngitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Lobomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Lower respiratory tract infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Lymphadenitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Malassezia infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mastitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis aspergillus
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis coccidioides
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis cryptococcal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis exserohilum
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis histoplasma
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Microsporum infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mucocutaneous candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mucormycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mycetoma mycotic
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mycotic corneal ulcer

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mycotic endophthalmitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Mycotoxicosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Myocarditis mycotic
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Nail candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Nasal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Necrotising fasciitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Neonatal candida infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Neoscytalidium infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Neurocryptococcosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Oesophageal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Onychomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Oral candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Oral fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Oro-pharyngeal aspergillosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Oropharyngeal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Oropharyngitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Osseous cryptococcosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Osteomyelitis blastomyces
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Osteomyelitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Otitis externa candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Otitis externa fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Overgrowth fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pancreatitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Paracoccidioides infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Penicillium infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis histoplasma
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Peritoneal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Phaeohyphomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Phaeohyphomycotic brain abscess
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumocystis jirovecii infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumocystis jirovecii pneumonia
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia blastomyces
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia cryptococcal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Presumed ocular histoplasmosis syndrome
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis monilial
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pseudallescheria infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pseudallescheria sepsis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary mucormycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary paracoccidioidomycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary sporotrichosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary trichosporonosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pyelonephritis fungal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Pythium insidiosum infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory moniliasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory tract infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Retinitis histoplasma
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Rhinocerebral mucormycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Rhinosporidiosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Scedosporium infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Scopulariopsis infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Severe asthma with fungal sensitisation
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Sinusitis aspergillus
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Sinusitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Skin candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Splenic candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Splenic infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Sporotrichosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Stoma site candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Superinfection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Systemic candida
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Systemic mycosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea barbae
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea blanca
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea capitis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea cruris
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea faciei
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea imbricata
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea manuum
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea nigra
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea pedis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tinea versicolour
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tongue fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Tonsillitis fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Torulopsis infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Trichophytic granuloma
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Trichophytosis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Trichosporon infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Upper respiratory fungal infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Urogenital infection fungal
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginal candidiasis
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginal mycotic infection
Severe infections	Fungal infectious disorders (HLGT)		ATOXGRN ge 3	Wound infection fungal
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Angiostrongylus infection
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Anisakiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Arthritis helminthic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Ascariasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Biliary tract infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Capillariasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Cestode infection
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Clonorchiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Cutaneous larva migrans
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Cystitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Dicrocoeliasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Diphyllobothriasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Dipylidiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Dirofilariasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Disseminated strongyloidiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Dracunculiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Echinococciasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Endocarditis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Enterobiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Enterocolitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Eye infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Fascioliasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Fasciolopsiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Filariasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Filariasis lymphatic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Gastritis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Genital infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Gnathostomiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Helminthic infection
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Hepatic echinococciasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Hepatic infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Heterophyiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Hookworm infection
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Hymenolepiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Lymphadenitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Meningoencephalitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Metagonimiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Myocarditis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Nematodiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Neurocysticercosis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Onchocerciasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Onchodermatitis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Opisthorchiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Oral helminthic infection
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Pancreatitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Paragonimiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Pericarditis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Peritonitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Pneumonia helminthic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Pulmonary echinococciasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Renal echinococciasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Schistosomiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Schistosomiasis bladder
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Schistosomiasis cutaneous
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Schistosomiasis liver
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Skin infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Splenic infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Strongyloidiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Syngamiasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Taeniasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Thyroid echinococciasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Toxocariasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Trematode infection
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Trichiniasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Trichostrongyliasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Trichuriasis
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Tropical eosinophilia
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Upper respiratory tract infection helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Vulvovaginitis helminthic
Severe infections	Helminthic disorders (HLGT)		ATOXGRN ge 3	Wound infection helminthic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abdominal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abdominal hernia infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abdominal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abdominal sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abdominal wall abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abdominal wall infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abortion infected
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess intestinal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess jaw
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess limb
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess neck
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess of external auditory meatus
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess of eyelid
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess of salivary gland
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess oral
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess rupture
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess soft tissue
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Abscess sweat gland
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Acne pustular
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Activated PI3 kinase delta syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Acute endocarditis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Acute sinusitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Adenoiditis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Administration site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Administration site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Administration site joint infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Administration site pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Adrenal gland abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Adrenalitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Alveolar osteitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Amniotic cavity infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Amniotic infection syndrome of Blane
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Anal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Anal fistula infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Anal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Anal papillitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Anastomotic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Anorectal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Appendiceal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Appendicitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Appendicitis perforated
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Application site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Application site folliculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Application site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Application site joint infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Application site pustules
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Arteriovenous fistula site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Arteriovenous graft site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Arteriovenous graft site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Arteritis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Arthritis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Atypical pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bacteraemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bacterial toxaemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bacterial translocation
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bacteroides bacteraemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Balanoposthitis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bartholin's abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bartholinitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bezold abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Biliary abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Biliary sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Biliary tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Biloma infected
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bladder diverticulitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Blebitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Blister infected
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bone abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Brain abscess

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Brain empyema
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Breast abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Breast discharge infected
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bronchitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Burn infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Bursitis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	CNS ventriculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Carbuncle
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cardiac infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cardiac valve abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cardiac valve vegetation
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Catheter site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Catheter site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Catheter site pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cavernous sinus thrombosis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cellulitis laryngeal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cellulitis pharyngeal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Central nervous system abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Central nervous system infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cerebral septic infarct
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cervicitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Chest wall abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cholangitis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cholecystitis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Chorioretinitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Chronic sinusitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Chronic tonsillitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Clitoris abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Coinfection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Colonic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Colostomy infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Complicated appendicitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Congenital infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Congenital pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Conjunctivitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Corneal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Corneal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cranial nerve infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cross infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Croup infectious
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Cystitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dacryocanaliculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dacryocystitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dental fistula
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dental gangrene
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dermatitis infected

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dermo-hypodermitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Device related bacteraemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Device related infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Device related sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Diabetic foot infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Diarrhoea infectious
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Diarrhoea infectious neonatal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Diverticulitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Diverticulitis intestinal haemorrhagic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Diverticulitis intestinal perforated
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Douglas' abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dural abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Dysentery
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ear infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ear lobe infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ecthyma
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eczema infected
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Embolic pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Emphysematous cholecystitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Emphysematous cystitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Emphysematous pyelonephritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Empyema
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Encephalitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Encephalitis brain stem
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Encephalitis lethargica
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Encephalomyelitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Endocarditis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Endometritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Endometritis decidual
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Endophthalmitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Endotoxaemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Endotoxic shock
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Enteritis infectious
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Enterocolitis infectious
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ependymitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Epididymitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Epiglottitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Epiglottitis obstructive
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Erysipeloid
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Extradural abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eye abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eye infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eye infection intraocular
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eyelid boil
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eyelid folliculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Eyelid infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Fallopian tube abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Fascial infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Febrile infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Focal peritonitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Fournier's gangrene
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Fracture infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Fungaemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Funisitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gallbladder abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gallbladder empyema
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gastric infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gastroenteritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gastrointestinal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Genital abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Genital infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Genital infection female
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Genital infection male
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Genital ulcer syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Genitourinary tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gingival abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gingivitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Gradenigo's syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Graft infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Groin abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Groin infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Haematoma infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Haemorrhagic pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Haemorrhoid infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hepatic cyst infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hepatic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hepatitis post transfusion
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hepatobiliary infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hepatosplenic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hordeolum
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hydrocele male infected
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Hypopyon
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Impetigo
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Implant site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Implant site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Implant site pustules
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Incision site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Induced abortion infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infantile septic granulomatosis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected bite
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected bunion
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected cyst

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected dermal cyst
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected fistula
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected gouty tophus
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected large intestinal ulcer
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected lymphocele
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected naevus
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected neoplasm
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected seroma
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected skin ulcer
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected urinoma
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected varicose vein
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infected vasculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infection in an immunocompromised host
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infection masked
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infection parasitic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infection reactivation
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infection susceptibility increased
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infectious crystalline keratopathy
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infectious iridocyclitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infectious pleural effusion
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infectious thyroiditis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective aneurysm
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective aortitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective chondritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective corneal ulcer
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective episcleritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective exacerbation of bronchiectasis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective exacerbation of chronic obstructive airways disease
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective glossitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective iritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective keratitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective mesenteric panniculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective myositis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective pericardial effusion
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective periostitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective pulmonary exacerbation of cystic fibrosis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective scleritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective spondylitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective tenosynovitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective thrombosis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infective uveitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infusion site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infusion site infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infusion site joint infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Infusion site pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Injection site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Injection site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Injection site joint infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Injection site pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Instillation site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Instillation site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Instillation site pustules
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Intervertebral discitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Intestinal fistula infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Intestinal sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Intracranial infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Intrauterine infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Joint abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Keratouveitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Kidney infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Labyrinthitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lacrimal gland abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Large intestine infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Laryngitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Laryngopharyngitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Laryngotracheitis obstructive
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lip infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Liver abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Localised infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lochial infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lower respiratory tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ludwig angina
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lung abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lymph gland infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lymph node abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Lymphangitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mastitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mastitis postpartum
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mastoid abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mastoid empyema
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mastoiditis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mediastinal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mediastinitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Medical device site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Medical device site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Medical device site joint infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Medical device site pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Meningitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Meningitis aseptic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Meningitis neonatal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mesenteric abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Miliary pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mononucleosis syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Mucosal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Muscle abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Myelitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Myocardiac abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Myocarditis infectious
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Myocarditis septic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Myometritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Myringitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Nail bed infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Nail infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Nasal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Nasal vestibulitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Nasopharyngitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Necrotising fasciitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Necrotising soft tissue infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neonatal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neonatal infective mastitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neonatal pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neovaginal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neurological infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neutropenic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Neutropenic sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Nipple infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Obstetric infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Oculoglandular syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Oesophageal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Oesophageal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Omphalitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Oophoritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ophthalmia neonatorum
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Opportunistic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Oral infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Oral pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Orbital infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Orchitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Osteomyelitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Osteomyelitis acute
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Osteomyelitis chronic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Otitis externa
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Otitis media
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Otitis media acute
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Otitis media chronic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Otosalpingitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ovarian abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Overgrowth of nonsusceptible organisms
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pancreas infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pancreatic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Panencephalitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Papillon-Lefevre syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Paracancerous pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parametric abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parametritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Paranasal mucopyocoele
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Paranasal sinus abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parapharyngeal space infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parasite allergy
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parasitic encephalitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parasitic gastroenteritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parasitic oesophagitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parasitic pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Paraspinal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parathyroid gland abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parotid abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Parotitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pathogen resistance
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pelvic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pelvic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pelvic inflammatory disease
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pelvic sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Penile abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Penile infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Peri-implantitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pericarditis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pericoronitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perihepatic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perihepatitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perineal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perineal cellulitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perineal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perinephric abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Periodontal destruction
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Periodontitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Periorbital abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Periorbital infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Peripheral nerve infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Perirectal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Peritoneal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Peritonitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Peritonsillar abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Peritonsillitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Periumbilical abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Petrositis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pharyngeal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pharyngeal pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pharyngitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pharyngolaryngeal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pharyngotonsillitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Phlebitis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pilonidal cyst
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pilonidal cyst congenital
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pitted keratolysis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pleural infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pneumonia necrotising
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Portal pyaemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Post abortion infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Post procedural infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Post procedural pneumonia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Post procedural sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Postoperative abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Postoperative wound infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Postpartum sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Prostate infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Prostatic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pseudoaneurysm infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Psoas abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Puerperal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Puerperal pyrexia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pulmonary sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pulpitis dental
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Puncture site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Puncture site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Purulence
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Purulent discharge
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Purulent pericarditis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Purulent synovitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyelitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyelocystitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyelonephritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyelonephritis acute
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyelonephritis chronic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyloric abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyoderma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyometra
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyonephrosis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyopneumothorax
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyospermia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Pyuria
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Rash pustular
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Rectal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Rectovaginal septum abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Recurrent pyogenic cholangitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Recurrent subareolar breast abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Renal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Renal cyst infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Renal graft infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Respiratory tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Retinitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Retroperitoneal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Retroperitoneal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Retroperitonitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Rhinitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Rhinolaryngitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Rhinotracheitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Root canal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Salpingitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Salpingo-oophoritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Scrotal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Scrotal cellulitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Scrotal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sebaceous gland infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Seminal vesicle abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Seminal vesicular infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sepsis neonatal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sepsis syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic coagulopathy
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic embolus
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic encephalopathy
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic necrosis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic phlebitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic pulmonary embolism
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic rash
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic shock
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Septic vasculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Shunt infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sialoadenitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sinobronchitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sinusitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Skin graft infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Skin infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Soft tissue infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Southern tick-associated rash illness
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Spermatic cord funiculitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Spinal cord abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Spinal cord infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Spinal empyema
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Splenic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Splenic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sputum purulent
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sternitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Stitch abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Stoma site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Stoma site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subacute endocarditis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subarachnoid abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subcutaneous abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subdiaphragmatic abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subdural abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subgaleal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subglottic laryngitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Subperiosteal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Superinfection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Sweat gland infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Systemic infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	TORCH infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Testicular abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Thrombophlebitis septic
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Thymus abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Thyroglossal cyst infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Thyroid gland abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tick-borne fever
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tongue abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tonsillitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tooth abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tooth infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tornwaldt bursitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Toxic shock syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tracheal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tracheitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tracheitis obstructive
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tracheobronchitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tracheostomy infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Transplant abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tropical infectious disease

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tropical ulcer
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Tubo-ovarian abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Umbilical sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Upper aerodigestive tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Upper respiratory tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urachal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ureter abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Ureteritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urethral abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urethral carbuncle
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urethral discharge syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urethral stricture post infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urethritis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urinary bladder abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urinary meatitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urinary tract abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urinary tract infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urinary tract infection neonatal
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Urosepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Uterine abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Uterine infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaccination site abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaccination site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaccination site joint infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaccination site pustule
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaccine breakthrough infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaginal abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vaginal infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vascular access site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vascular device infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vascular graft infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vessel puncture site infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vestibulitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Viraemia
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Virologic failure
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Visceral larva migrans
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vitreous abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vitritis infective
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vulval abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vulvitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Vulvovaginitis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Wound abscess
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Wound infection
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Wound sepsis
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Young's syndrome
Severe infections	Infections - pathogen unspecified (HLGT)		ATOXGRN ge 3	Zoonosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Adrenal gland tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Atypical mycobacterial infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Atypical mycobacterial lower respiratory tract infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Atypical mycobacterial lymphadenitis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Atypical mycobacterial pneumonia
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Atypical mycobacterium pericarditis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bone tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Borderline leprosy
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Bovine tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Choroid tubercles
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Congenital tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Conjunctivitis tuberculous
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated Bacillus Calmette-Guerin infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated mycobacterium avium complex infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Ear tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Epididymitis tuberculous
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Erythema induratum
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Extrapulmonary tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Female genital tract tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Immune reconstitution inflammatory syndrome associated tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Indeterminate leprosy
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Intestinal tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Joint tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Latent tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lepromatous leprosy
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Leprosy
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lupus vulgaris
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Lymph node tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Male genital tract tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mammary tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis tuberculous
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterial infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterial peritonitis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium abscessus infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium avium complex immune restoration disease
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium avium complex infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium chelonae infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium fortuitum infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium haemophilum infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium kansasii infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium marinum infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Mycobacterium ulcerans infection
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Oesophageal tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Oral tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis tuberculous
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Peritoneal tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Prostatitis tuberculous
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary tuberculoma
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Pulmonary tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Renal tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Salpingitis tuberculous
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Silicotuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Spleen tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Superinfection mycobacterial
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Thyroid tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculoid leprosy
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculoma of central nervous system
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis bladder
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis gastrointestinal
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis liver
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis of central nervous system
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis of eye
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis of genitourinary system
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis of intrathoracic lymph nodes
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis of peripheral lymph nodes
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculosis ureter
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculous endometritis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculous laryngitis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculous pleurisy
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Tuberculous tenosynovitis
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Type 1 lepra reaction
Severe infections	Mycobacterial infectious disorders (HLGT)		ATOXGRN ge 3	Type 2 lepra reaction
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Cervicitis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Epididymitis ureaplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Mycoplasma genitalium infection
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Mycoplasma infection
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Mycoplasmal postabortal fever
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Mycoplasmal postpartum fever
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Pelvic inflammatory disease mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Pharyngitis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia mycoplasmal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Pyelonephritis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Tracheobronchitis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Ureaplasma cervicitis
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Ureaplasma infection
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Ureaplasmal vulvovaginitis
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Urethritis mycoplasmal
Severe infections	Mycoplasmal infectious disorders (HLGT)		ATOXGRN ge 3	Urethritis ureaplasmal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Acanthamoeba infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Acanthamoeba keratitis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	African trypanosomiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	American trypanosomiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Amoebiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Amoebic brain abscess
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Amoebic colitis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Amoebic dysentery
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Amoebic lung abscess
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Amoebic skin ulcer
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Babesiosis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Balamuthia infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Balantidiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Biliary tract infection cryptosporidial
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Blackwater fever
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Blastocystis infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Cerebral malaria
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Cerebral toxoplasmosis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Cervicitis trichomonal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Chagas' cardiomyopathy
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Chagoma
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Congenital malaria
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Congenital toxoplasmosis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Cryptosporidiosis infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Cutaneous leishmaniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Cyclosporidium infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Dientamoeba infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated leishmaniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated toxoplasmosis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis protozoal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection toxoplasmal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis cryptosporidial
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal protozoal infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Giardiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Hepatic amoebiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis toxoplasmal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Infection protozoal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Isosporiasis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Leishmaniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Malaria
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Malaria recrudescence
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Malaria relapse
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Malarial myocarditis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis toxoplasmal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis trypanosomal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Meningoencephalitis amoebic
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Microsporidia infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Mucocutaneous leishmaniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Myocarditis toxoplasmal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Naegleria infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Pericarditis amoebic
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Plasmodium falciparum infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Plasmodium knowlesi infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Plasmodium malariae infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Plasmodium ovale infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Plasmodium vivax infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia toxoplasmal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Prostatitis trichomonal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Protothecosis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Protozoal corneal ulcer
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Romana’s sign
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Sarcocystis infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Toxoplasmosis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Trichomoniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Trichomoniasis intestinal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Trypanosomiasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Urethritis trichomonal
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Urogenital trichomoniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Visceral leishmaniasis
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Vorticella infection
Severe infections	Protozoal infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginitis trichomonal
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Boutonneuse fever
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Coxiella infection
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis rickettsial
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis Q fever
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Epidemic typhus
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Human anaplasmosis
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Human ehrlichiosis
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Japanese spotted fever
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Murine typhus
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	North Asian tick typhus
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Q fever
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Queensland tick typhus
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Recrudescent typhus

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Rickettsialpox
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Rickettsioses not tick borne
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Rickettsiosis
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Rocky mountain spotted fever
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Scrub typhus
Severe infections	Rickettsial infectious disorders (HLGT)		ATOXGRN ge 3	Typhus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	AIDS cholangiopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	AIDS dysmorphic syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	AIDS related complex
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	AIDS related complication
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	AIDS retinopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Acquired immunodeficiency syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Acute HIV infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Acute haemorrhagic conjunctivitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Acute hepatitis B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Acute hepatitis C
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenoviral conjunctivitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenoviral encephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenoviral haemorrhagic cystitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenoviral hepatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenoviral meningitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenoviral upper respiratory infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenovirus encephalomyeloradiculitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Adenovirus reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Alongshan virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Alphaviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Anogenital warts
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Anorectal human papilloma virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Arboviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Arenaviral haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Argentine haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Arthritis rubella
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Arthritis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Asymptomatic COVID-19
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Asymptomatic HIV infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Asymptomatic viral hepatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Avian influenza
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	BK virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Biliary tract infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Blepharal papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Bolivian haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Boston exanthema
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Bovine pustular stomatitis virus infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Bronchiolitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Bronchitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Bulbar poliomyelitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Buschke-Lowenstein's tumour
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	COVID-19
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	COVID-19 pneumonia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	CSF HIV escape syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cataract congenital
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Central nervous system enteroviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Central nervous system viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cervicitis human papilloma virus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cervix warts
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Chikungunya virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Choriomeningitis lymphocytic
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Chronic active Epstein-Barr virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Chronic hepatitis B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Chronic hepatitis C
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Colitis herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Colorado tick fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital COVID-19
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital Ebola virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital HIV infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital Zika syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital condyloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital cytomegalovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital dengue disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital hepatitis B infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital hepatitis C infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital herpes simplex infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital rubella infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital rubella syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital varicella infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congenital viral hepatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Congo-Crimean haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Conjunctivitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coronavirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cow pox
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie bronchitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie carditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie endocarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie myocarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie pericarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie viral disease of the newborn
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Coxsackie viral infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Creutzfeldt-Jakob disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cystitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus chorioretinitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus colitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus duodenitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus enteritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus enterocolitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus gastritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus gastroenteritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus gastrointestinal infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus gastrointestinal ulcer
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus hepatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus infection reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus mononucleosis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus mucocutaneous ulcer
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus myelomeningoradiculitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus myocarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus nephritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus oesophagitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus pancreatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus pericarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus urinary tract infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Cytomegalovirus viraemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Dengue fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Dengue haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated cytomegaloviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated neonatal herpes simplex
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated varicella
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated varicella zoster vaccine virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Disseminated varicella zoster virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Ear infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Ebola Reston virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Ebola disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Echo virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Eczema Coxsackium
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Eczema herpeticum
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Eczema vaccinatum
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis Japanese B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis australia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis california
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis cytomegalovirus

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis eastern equine
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis enteroviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis influenzal
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis venezuelan equine
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalitis western equine
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Encephalomyelitis rubella
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	End stage AIDS
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Endocarditis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Enterocolitis AIDS
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Enterocolitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Enterovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Enterovirus myocarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epidemic pleurodynia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epidemic polyarthritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epidermodysplasia verruciformis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epididymitis mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epstein Barr virus positive mucocutaneous ulcer
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epstein-Barr viraemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epstein-Barr virus associated lymphoma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epstein-Barr virus associated lymphoproliferative disorder
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epstein-Barr virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Epstein-Barr virus infection reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Eruptive pseudoangiomatosis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Erythema infectiosum
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Exanthema subitum
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Eye infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Fatal familial insomnia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Filovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Flavivirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Focal epithelial hyperplasia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Foot and mouth disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastritis herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastritis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis adenovirus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis astroviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis caliciviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis enteroviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis norovirus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis rotavirus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis sapovirus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastroenteritis viral

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gastrointestinal viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Generalised vaccinia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Genital herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Genital herpes simplex
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Genital herpes zoster
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Genital infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gerstmann Straussler Scheinker syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Gianotti-Crosti syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	H1N1 influenza
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	H2N2 influenza
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	H3N2 influenza
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HCoV-229E infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HCoV-HKU1 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HCoV-NL63 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HCoV-OC43 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV associated nephropathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV cardiomyopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV enteropathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group I
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group II
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group III
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group IV subgroup A
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group IV subgroup B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group IV subgroup C1
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group IV subgroup C2
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group IV subgroup D
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC Group IV subgroup E
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC category A
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC category B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC category C
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection CDC group IV
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection WHO clinical stage I
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection WHO clinical stage II
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection WHO clinical stage III
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV infection WHO clinical stage IV
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV lipodystrophy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV meningoencephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV peripheral neuropathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV viraemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV wasting syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV-2 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	HIV-associated neurocognitive disorder
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Haemorrhagic fever with renal syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Haemorrhagic varicella syndrome

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hand-foot-and-mouth disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hantaviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hantavirus pulmonary infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Heartland virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis A
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis B reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis C
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis D
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis E
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis F
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis G
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis H
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis infectious mononucleosis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis non-A non-B
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis non-A non-B non-C
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Hepatitis virus-associated nephropathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpangina
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes dermatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes oesophagitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes ophthalmic
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes pharyngitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes sepsis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex bronchitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex cervicitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex colitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex encephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex gastritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex hepatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex meningitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex meningoencephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex meningomyelitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex necrotising retinopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex oesophagitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex otitis externa
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex pharyngitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex pneumonia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex sepsis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex viraemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex virus conjunctivitis neonatal
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes simplex visceral

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster cutaneous disseminated
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster infection neurological
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster meningitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster meningoencephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster meningomyelitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster meningoradiculitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster necrotising retinopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster oticus
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster pharyngitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpes zoster reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Herpetic radiculopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human T-cell lymphocytic virus type II infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human T-cell lymphotropic virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human T-cell lymphotropic virus type I infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human bocavirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human herpesvirus 6 encephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human herpesvirus 6 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human herpesvirus 6 infection reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human herpesvirus 7 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human herpesvirus 8 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Human polyomavirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Immune reconstitution inflammatory syndrome associated Kaposi’s sarcoma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Infectious mononucleosis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Influenza
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	JC virus granule cell neuronopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	JC virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Kaposi sarcoma inflammatory cytokine syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Kaposi’s sarcoma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Kaposi’s sarcoma AIDS related
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Keratitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Keratoconjunctivitis measles
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Kuru
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Kyasanur Forest disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Laryngeal papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Laryngitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Lassa fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Louping ill
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Lower respiratory tract herpes infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Lower respiratory tract infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Lujo haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Lymphadenitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Lymphoma AIDS related
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Marburg disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Measles
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Measles meningitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Measles post vaccine
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis coxsackie viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis echo viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis enteroviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningoencephalitis herpes simplex neonatal
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningoencephalitis herpetic
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningoencephalitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Meningomyelitis herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Merkel cell polyomavirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Metapneumovirus bronchiolitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Metapneumovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Metapneumovirus pneumonia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Middle East respiratory syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Milker's nodules
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Molluscum contagiosum
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Monkeypox
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Mumps deafness
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Murray Valley encephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Nail bed infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Nasal herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Necrotising herpetic retinopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Neonatal mucocutaneous herpes simplex
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Newcastle disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Nipah virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Norovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	O'nyong-nyong fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Omsk haemorrhagic fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Ophthalmic herpes simplex
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Ophthalmic herpes zoster
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Oral hairy leukoplakia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Oral herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Oral papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Oral viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Orbivirus infection

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Orchitis mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Orf
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Oropouche fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Orthopox virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Osteomyelitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Otitis externa viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media post measles
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Otitis media viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pancreatitis mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pancreatitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Papilloma viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Papular pruritic eruption of HIV
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parainfluenzae viral bronchitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parainfluenzae viral laryngotracheobronchitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parainfluenzae virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parapox virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Paravaccinia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parechovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parvovirus B19 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parvovirus B19 infection reactivation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Parvovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Penile wart
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Perinatal HBV infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Perinatal HIV infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Peritonitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Persistent generalised lymphadenopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pharyngoconjunctival fever of children
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Phlebotomus fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Picornavirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pleurisy viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia adenoviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia cytomegaloviral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia herpes viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia influenzal
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia measles
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia parainfluenzae viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia respiratory syncytial viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pneumonia viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pogosta disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Polioencephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Poliomyelitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Polyneuropathy mumps
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Polyomavirus viraemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Polyomavirus-associated nephropathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Post measles blindness

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Post transplant lymphoproliferative disorder
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Post vaccination autoinoculation
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Post viral fatigue syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Post-acute COVID-19 syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Prion disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Proctitis herpes
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Progressive multifocal leukoencephalopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Progressive vaccinia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Pyelonephritis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rabies
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Reoviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory syncytial virus bronchiolitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory syncytial virus bronchitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory syncytial virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Respiratory tract infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Retinitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Retroviral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Retroviral rebound syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rhinovirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rift Valley fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rocio virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rotavirus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rubella
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rubella in pregnancy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Rubella infection neurological
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	SARS-CoV-2 sepsis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	SARS-CoV-2 viraemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Severe acute respiratory syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Severe fever with thrombocytopenia syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Sinonasal papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Skin papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Slow virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Smallpox
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Snowshoe hare virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Splenic infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	St. Louis encephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Superinfection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Suspected COVID-19
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Sweating fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Systemic viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	T-cell lymphoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	T-cell type acute leukaemia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Tick-borne viral encephalitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Tracheal papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Tracheobronchitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Tropical spastic paresis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Urethral papilloma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Urinary tract infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vaccine associated paralytic poliomyelitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vaccine derived SARS-CoV-2 infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vaccinia virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vaginitis viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Variant Creutzfeldt-Jakob disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella keratitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella post vaccine
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella zoster gastritis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella zoster oesophagitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella zoster pneumonia
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella zoster sepsis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Varicella zoster virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vestibular neuronitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral acanthoma
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral cardiomyopathy
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral corneal ulcer
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral diarrhoea
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral epiglottitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral haemorrhagic cystitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral keratouveitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral labyrinthitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral mastitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral myelitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral myocarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral myositis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral oesophagitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral parotitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral pericarditis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral pharyngitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral rash
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral rhinitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral sepsis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral sinusitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral skin infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral tonsillitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral tracheitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral upper respiratory tract infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral uveitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Viral vasculitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginal human papilloma virus infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Vulvovaginal warts
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	West Nile viral infection
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Withdrawal hepatitis
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Wound infection viral
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	X-linked lymphoproliferative syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Yellow fever
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Yellow fever vaccine-associated neurotropic disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Yellow fever vaccine-associated viscerotropic disease
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Zika virus associated Guillain Barre syndrome
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Zika virus associated birth defect
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Zika virus associated microencephaly
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Zika virus associated ocular birth defect
Severe infections	Viral infectious disorders (HLGT)		ATOXGRN ge 3	Zika virus infection
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Anaphylactic reaction
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Anaphylactic shock
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Anaphylactic transfusion reaction
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Anaphylactoid reaction
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Anaphylactoid shock
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Circulatory collapse
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Dialysis membrane reaction
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Kounis syndrome
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Procedural shock
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Shock
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Shock symptom
Hypersensitivity 'ALL'	Anaphylactic reaction (SMQ)	NARROW		Type I hypersensitivity
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Acquired C1 inhibitor deficiency
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Allergic oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Angioedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Circumoral oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Circumoral swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Conjunctival oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Corneal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Epiglottic oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Eye oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Eye swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Eyelid oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Face oedema

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Gingival oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Gingival swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Gleich's syndrome
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Hereditary angioedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Hereditary angioedema with C1 esterase inhibitor deficiency
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Hereditary angioedema with normal C1 esterase inhibitor
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Idiopathic angioedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Idiopathic urticaria
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Intestinal angioedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Laryngeal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Laryngotracheal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Limbal swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Lip oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Lip swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Mouth swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Oculorespiratory syndrome
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Oedema mouth
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Oropharyngeal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Oropharyngeal swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Palatal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Palatal swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Periorbital oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Periorbital swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Pharyngeal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Pharyngeal swelling
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Scleral oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Swelling face
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Swelling of eyelid
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Swollen tongue
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Tongue oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Tracheal oedema
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Urticaria
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Urticaria cholinergic
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Urticaria chronic
Hypersensitivity 'ALL'	Angioedema (SMQ)	NARROW		Urticaria papular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Acquired C1 inhibitor deficiency
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Acute generalised exanthematous pustulosis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration related reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site recall reaction

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Administration site vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic bronchitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic colitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic cough
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic cystitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic eosinophilia
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic gastroenteritis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic hepatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic keratitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic otitis externa
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic otitis media
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic pharyngitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic reaction to excipient
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic respiratory disease
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic respiratory symptom
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic sinusitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic stomatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergic transfusion reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergy alert test positive
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergy test positive
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergy to immunoglobulin therapy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergy to surgical sutures
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Allergy to vaccine
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anal eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anaphylactic reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anaphylactic shock
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anaphylactic transfusion reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anaphylactoid reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anaphylactoid shock
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anaphylaxis treatment
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Angioedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Anti-neutrophil cytoplasmic antibody positive vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Antiallergic therapy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Antiendomysial antibody positive
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site recall reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Application site vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Arthritis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Aspirin-exacerbated respiratory disease

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Atopic cough
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Atopy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Blepharitis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Blood immunoglobulin E abnormal
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Blood immunoglobulin E increased
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Bromoderma
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Bronchospasm
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Bullous haemorrhagic dermatosis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Catheter site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Catheter site eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Catheter site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Catheter site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Catheter site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Catheter site vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Chronic eosinophilic rhinosinusitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Chronic hyperplastic eosinophilic sinusitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Circulatory collapse
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Circumoral oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Circumoral swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Conjunctival oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Conjunctivitis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Contact stomatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Contrast media allergy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Contrast media reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Corneal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Cross sensitivity reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Cutaneous vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dennie-Morgan fold
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis acneiform
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis atopic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis bullous
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis contact
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis exfoliative
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis exfoliative generalised
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis herpetiformis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis infected
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dermatitis psoriasiform
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Device allergy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Dialysis membrane reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Distributive shock
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Documented hypersensitivity to administered product
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Drug eruption

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Drug hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Drug provocation test
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Drug reaction with eosinophilia and systemic symptoms
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eczema infantile
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eczema nummular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eczema vaccinatum
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eczema vesicular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eczema weeping
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Encephalitis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Encephalopathy allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eosinophilic granulomatosis with polyangiitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Epidermal necrosis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Epidermolysis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Epidermolysis bullosa
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Epiglottic oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Erythema multiforme
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Erythema nodosum
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Exfoliative rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eye allergy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eye oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eye swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Eyelid oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Face oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Fixed eruption
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Generalised bullous fixed drug eruption
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Giant papillary conjunctivitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Gingival oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Gingival swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Gleich's syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Haemorrhagic urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Hand dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Henoch-Schonlein purpura
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Henoch-Schonlein purpura nephritis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Heparin-induced thrombocytopenia
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Hypersensitivity myocarditis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Hypersensitivity pneumonitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Hypersensitivity vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Idiopathic urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Immediate post-injection reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Immune thrombocytopenia
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Immune tolerance induction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Implant site dermatitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Implant site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Implant site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Implant site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Incision site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Incision site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion related hypersensitivity reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion related reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site recall reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Infusion site vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection related reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site recall reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Injection site vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Instillation site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Instillation site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Instillation site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Interstitial granulomatous dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Intestinal angioedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Iodine allergy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Kounis syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Laryngeal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Laryngitis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Laryngospasm
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Laryngotracheal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Limbal swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Lip oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Lip swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Mast cell activation syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Mast cell degranulation present
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Medical device site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Medical device site eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Medical device site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Medical device site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Medical device site recall reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Medical device site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Mouth swelling

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Mucocutaneous rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Multiple allergies
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Nephritis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Nikolsky's sign
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Nodular rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Nutritional supplement allergy
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oculomucocutaneous syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oculorespiratory syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oedema mouth
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oral allergy syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oropharyngeal blistering
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oropharyngeal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oropharyngeal spasm
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Oropharyngeal swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Palatal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Palatal swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Palisaded neutrophilic granulomatous dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Palpable purpura
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Pathergy reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Perioral dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Periorbital oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Periorbital swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Pharyngeal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Pharyngeal swelling
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Procedural shock
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Pruritus allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Radioallergosorbent test positive
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash erythematous
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash follicular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash macular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash maculo-papular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash maculovesicular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash morbilliform
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash neonatal
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash papulosquamous
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash pruritic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash pustular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash rubelliform
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash scarlatiniform
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rash vesicular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Reaction to azo-dyes
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Reaction to colouring
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Reaction to excipient
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Reaction to food additive

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Reaction to preservatives
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Red man syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Rhinitis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		SJS-TEN overlap
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Scleral oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Scleritis allergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Scrotal dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Scrotal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Serum sickness
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Serum sickness-like reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Shock
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Shock symptom
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Skin necrosis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Skin reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Skin test positive
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Solar urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Solvent sensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Stevens-Johnson syndrome
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Stoma site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Stoma site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Swelling face
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Swelling of eyelid
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Swollen tongue
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Symmetrical drug-related intertriginous and flexural exanthema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Tongue oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Toxic epidermal necrolysis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Toxic skin eruption
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Tracheal oedema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Type I hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Type II hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Type III immune complex mediated reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Type IV hypersensitivity reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria cholinergic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria chronic
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria contact
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria papular
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria physical
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria pigmentosa
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticaria vesiculosa
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticarial dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Urticarial vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site dermatitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site eczema

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site exfoliation
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site hypersensitivity
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site recall reaction
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site urticaria
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site vasculitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaccination site vesicles
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vaginal ulceration
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vasculitic rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vernal keratoconjunctivitis
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vessel puncture site rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vessel puncture site vesicles
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vulval eczema
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vulval ulceration
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vulvovaginal rash
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vulvovaginal ulceration
Hypersensitivity 'ALL'	Hypersensitivity (SMQ)	NARROW		Vulvovaginitis allergic
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Anaphylactic reaction
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Anaphylactic shock
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Anaphylactic transfusion reaction
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Anaphylactoid reaction
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Anaphylactoid shock
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Circulatory collapse
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Dialysis membrane reaction
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Kounis syndrome
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Procedural shock
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Shock
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Shock symptom
Anaphylactic reaction	Anaphylactic reaction (SMQ)	NARROW		Type I hypersensitivity
Angioedema	Angioedema (SMQ)	NARROW		Acquired C1 inhibitor deficiency
Angioedema	Angioedema (SMQ)	NARROW		Allergic oedema
Angioedema	Angioedema (SMQ)	NARROW		Angioedema
Angioedema	Angioedema (SMQ)	NARROW		Circumoral oedema
Angioedema	Angioedema (SMQ)	NARROW		Circumoral swelling
Angioedema	Angioedema (SMQ)	NARROW		Conjunctival oedema
Angioedema	Angioedema (SMQ)	NARROW		Corneal oedema
Angioedema	Angioedema (SMQ)	NARROW		Epiglottic oedema
Angioedema	Angioedema (SMQ)	NARROW		Eye oedema
Angioedema	Angioedema (SMQ)	NARROW		Eye swelling
Angioedema	Angioedema (SMQ)	NARROW		Eyelid oedema
Angioedema	Angioedema (SMQ)	NARROW		Face oedema
Angioedema	Angioedema (SMQ)	NARROW		Gingival oedema
Angioedema	Angioedema (SMQ)	NARROW		Gingival swelling
Angioedema	Angioedema (SMQ)	NARROW		Gleich's syndrome
Angioedema	Angioedema (SMQ)	NARROW		Hereditary angioedema

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Angioedema	Angioedema (SMQ)	NARROW		Hereditary angioedema with C1 esterase inhibitor deficiency
Angioedema	Angioedema (SMQ)	NARROW		Hereditary angioedema with normal C1 esterase inhibitor
Angioedema	Angioedema (SMQ)	NARROW		Idiopathic angioedema
Angioedema	Angioedema (SMQ)	NARROW		Idiopathic urticaria
Angioedema	Angioedema (SMQ)	NARROW		Intestinal angioedema
Angioedema	Angioedema (SMQ)	NARROW		Laryngeal oedema
Angioedema	Angioedema (SMQ)	NARROW		Laryngotracheal oedema
Angioedema	Angioedema (SMQ)	NARROW		Limbal swelling
Angioedema	Angioedema (SMQ)	NARROW		Lip oedema
Angioedema	Angioedema (SMQ)	NARROW		Lip swelling
Angioedema	Angioedema (SMQ)	NARROW		Mouth swelling
Angioedema	Angioedema (SMQ)	NARROW		Oculorespiratory syndrome
Angioedema	Angioedema (SMQ)	NARROW		Oedema mouth
Angioedema	Angioedema (SMQ)	NARROW		Oropharyngeal oedema
Angioedema	Angioedema (SMQ)	NARROW		Oropharyngeal swelling
Angioedema	Angioedema (SMQ)	NARROW		Palatal oedema
Angioedema	Angioedema (SMQ)	NARROW		Palatal swelling
Angioedema	Angioedema (SMQ)	NARROW		Periorbital oedema
Angioedema	Angioedema (SMQ)	NARROW		Periorbital swelling
Angioedema	Angioedema (SMQ)	NARROW		Pharyngeal oedema
Angioedema	Angioedema (SMQ)	NARROW		Pharyngeal swelling
Angioedema	Angioedema (SMQ)	NARROW		Scleral oedema
Angioedema	Angioedema (SMQ)	NARROW		Swelling face
Angioedema	Angioedema (SMQ)	NARROW		Swelling of eyelid
Angioedema	Angioedema (SMQ)	NARROW		Swollen tongue
Angioedema	Angioedema (SMQ)	NARROW		Tongue oedema
Angioedema	Angioedema (SMQ)	NARROW		Tracheal oedema
Angioedema	Angioedema (SMQ)	NARROW		Urticaria
Angioedema	Angioedema (SMQ)	NARROW		Urticaria cholinergic
Angioedema	Angioedema (SMQ)	NARROW		Urticaria chronic
Angioedema	Angioedema (SMQ)	NARROW		Urticaria papular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Acquired C1 inhibitor deficiency
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Acute generalised exanthematous pustulosis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration related reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site recall reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Administration site vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic bronchitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic colitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic cough
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic cystitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic eosinophilia
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic gastroenteritis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic hepatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic keratitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic otitis externa
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic otitis media
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic pharyngitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic reaction to excipient
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic respiratory disease
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic respiratory symptom
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic sinusitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic stomatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergic transfusion reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergy alert test positive
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergy test positive
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergy to immunoglobulin therapy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergy to surgical sutures
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Allergy to vaccine
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anal eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anaphylactic reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anaphylactic shock
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anaphylactic transfusion reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anaphylactoid reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anaphylactoid shock
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anaphylaxis treatment
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Angioedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Anti-neutrophil cytoplasmic antibody positive vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Antiallergic therapy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Antiendomysial antibody positive
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site recall reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Application site vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Arthritis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Aspirin-exacerbated respiratory disease
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Atopic cough
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Atopy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Blepharitis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Blood immunoglobulin E abnormal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Blood immunoglobulin E increased
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Bromoderma
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Bronchospasm
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Bullous haemorrhagic dermatosis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Catheter site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Catheter site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Catheter site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Catheter site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Catheter site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Catheter site vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Chronic eosinophilic rhinosinusitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Chronic hyperplastic eosinophilic sinusitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Circulatory collapse
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Circumoral oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Circumoral swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Conjunctival oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Conjunctivitis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Contact stomatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Contrast media allergy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Contrast media reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Corneal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Cross sensitivity reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Cutaneous vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dennie-Morgan fold
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis acneiform
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis atopic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis bullous
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis contact
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis exfoliative
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis exfoliative generalised
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis herpetiformis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis infected
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dermatitis psoriasiform
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Device allergy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Dialysis membrane reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Distributive shock
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Documented hypersensitivity to administered product
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Drug eruption
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Drug hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Drug provocation test
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Drug reaction with eosinophilia and systemic symptoms

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eczema infantile
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eczema nummular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eczema vaccinatum
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eczema vesicular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eczema weeping
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Encephalitis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Encephalopathy allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eosinophilic granulomatosis with polyangiitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Epidermal necrosis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Epidermolysis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Epidermolysis bullosa
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Epiglottic oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Erythema multiforme
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Erythema nodosum
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Exfoliative rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eye allergy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eye oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eye swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Eyelid oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Face oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Fixed eruption
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Generalised bullous fixed drug eruption
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Giant papillary conjunctivitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Gingival oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Gingival swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Gleich's syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Haemorrhagic urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Hand dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Henoch-Schonlein purpura
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Henoch-Schonlein purpura nephritis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Heparin-induced thrombocytopenia
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Hypersensitivity myocarditis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Hypersensitivity pneumonitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Hypersensitivity vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Idiopathic urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Immediate post-injection reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Immune thrombocytopenia
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Immune tolerance induction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Implant site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Implant site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Implant site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Implant site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Incision site dermatitis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Incision site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion related hypersensitivity reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion related reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site recall reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Infusion site vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection related reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site recall reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Injection site vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Instillation site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Instillation site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Instillation site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Interstitial granulomatous dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Intestinal angioedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Iodine allergy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Kounis syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Laryngeal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Laryngitis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Laryngospasm
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Laryngotracheal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Limbal swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Lip oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Lip swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Mast cell activation syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Mast cell degranulation present
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Medical device site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Medical device site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Medical device site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Medical device site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Medical device site recall reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Medical device site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Mouth swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Mucocutaneous rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Multiple allergies
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Nephritis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Nikolsky's sign

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Nodular rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Nutritional supplement allergy
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oculomucocutaneous syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oculorespiratory syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oedema mouth
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oral allergy syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oropharyngeal blistering
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oropharyngeal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oropharyngeal spasm
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Oropharyngeal swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Palatal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Palatal swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Palisaded neutrophilic granulomatous dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Palpable purpura
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Pathergy reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Perioral dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Periorbital oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Periorbital swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Pharyngeal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Pharyngeal swelling
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Procedural shock
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Pruritus allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Radioallergosorbent test positive
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash erythematous
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash follicular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash macular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash maculo-papular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash maculovesicular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash morbilliform
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash neonatal
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash papulosquamous
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash pruritic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash pustular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash rubelliform
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash scarlatiniform
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rash vesicular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Reaction to azo-dyes
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Reaction to colouring
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Reaction to excipient
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Reaction to food additive
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Reaction to preservatives
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Red man syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Rhinitis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		SJS-TEN overlap

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Scleral oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Scleritis allergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Scrotal dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Scrotal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Serum sickness
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Serum sickness-like reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Shock
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Shock symptom
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Skin necrosis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Skin reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Skin test positive
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Solar urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Solvent sensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Stevens-Johnson syndrome
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Stoma site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Stoma site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Swelling face
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Swelling of eyelid
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Swollen tongue
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Symmetrical drug-related intertriginous and flexural exanthema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Tongue oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Toxic epidermal necrolysis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Toxic skin eruption
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Tracheal oedema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Type I hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Type II hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Type III immune complex mediated reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Type IV hypersensitivity reaction
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria cholinergic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria chronic
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria contact
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria papular
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria physical
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria pigmentosa
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticaria vesiculosa
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticarial dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Urticarial vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site dermatitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site exfoliation
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site hypersensitivity
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site recall reaction

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site urticaria
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site vasculitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaccination site vesicles
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vaginal ulceration
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vasculitic rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vernal keratoconjunctivitis
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vessel puncture site rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vessel puncture site vesicles
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vulval eczema
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vulval ulceration
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vulvovaginal rash
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vulvovaginal ulceration
Hypersensitivity	Hypersensitivity (SMQ)	NARROW		Vulvovaginitis allergic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		5q minus syndrome
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute bilineal leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute biphenotypic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute erythroid leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute leukaemia in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute lymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute lymphocytic leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute lymphocytic leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute lymphocytic leukaemia refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute megakaryocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute megakaryocytic leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute monocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute monocytic leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute myeloid leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute myeloid leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute myeloid leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute myeloid leukaemia refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute myelomonocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute promyelocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Acute undifferentiated leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Adult T-cell lymphoma/leukaemia stage IV

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Aleukaemic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large cell lymphoma T- and null-cell types stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Anaplastic large-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angiocentric lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Angioimmunoblastic T-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B precursor type acute leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell prolymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell small lymphocytic lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell type acute leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell unclassifiable lymphoma high grade
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		B-cell unclassifiable lymphoma low grade
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Blast cell crisis
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Blast crisis in myelogenous leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Blastic plasmacytoid dendritic cell neoplasia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Bone marrow leukaemic cell infiltration
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Bone marrow tumour cell infiltration
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Breast implant-associated anaplastic large cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Burkitt's lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Central nervous system leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Central nervous system lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chloroma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chloroma (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic eosinophilic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic leukaemia in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia stage 0
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia stage 1

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia stage 2
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia stage 3
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia stage 4
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic lymphocytic leukaemia transformation
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myeloid leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myeloid leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myeloid leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myeloid leukaemia transformation
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myelomonocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myelomonocytic leukaemia (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Chronic myelomonocytic leukaemia with N-ras gene mutation
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Composite lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous T-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Cutaneous lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Diffuse large B-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Disseminated large cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Double hit lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Enteropathy-associated T-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Eosinophilic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Epstein-Barr virus associated lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Erythraemic myelosis (in remission)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (BALT type)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type)
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type) recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type) refractory

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type) stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type) stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type) stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Extranodal marginal zone B-cell lymphoma (MALT type) stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma diffuse small cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicle centre lymphoma, follicular grade I, II, III stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicular dendritic cell sarcoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicular lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicular lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicular lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicular lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Follicular lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Gastrointestinal lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Grey zone lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Haematological malignancy
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hairy cell leukaemia

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Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hairy cell leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hepatosplenic T-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High grade B-cell lymphoma Burkitt-like lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		High-grade B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Histiocytic medullary reticulosis
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Histiocytic sarcoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion stage I site unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion stage I subdiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion stage I supradiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion stage II site unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion stage II subdiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion stage II supradiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion type recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion type refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion type stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion type stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte depletion type stage unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte predominance stage I site unspec
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin’s disease lymphocyte predominance stage I subdiaphragm

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance stage I supradiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance stage II site unspec
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance stage II subdiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance stage II supradiaphragm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance type recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance type refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance type stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance type stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease lymphocyte predominance type stage unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage I site unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage I subdiaphragmatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage I supradiaphragmatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage II subdiaphragmatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage II supradiaphragmatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease mixed cellularity stage unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis stage I

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease nodular sclerosis stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Hodgkin's disease unclassifiable
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Immunoblastic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Intestinal T-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Intestinal T-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Intestinal T-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Intestinal T-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Intestinal T-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Intestinal T-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Juvenile chronic myelomonocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leptomeningeal myelomatosis
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia basophilic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia cutis
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia granulocytic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia monocytic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic cardiac infiltration
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration extramedullary
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration gingiva
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration hepatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration ovary
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration pulmonary
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic infiltration renal
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Leukaemic retinopathy
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lineage switch leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphangiosarcoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphangiosis carcinomatosa
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphocytic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoid leukaemia (in remission)

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoma AIDS related
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoma transformation
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Lymphoplasmacytoid lymphoma/immunocytoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant histiocytosis
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant lymphoid neoplasm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant lymphoma unclassifiable high grade
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant lymphoma unclassifiable low grade
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant mast cell neoplasm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of thymus
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Malignant splenic neoplasm
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mantle cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Marginal zone lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mastocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Mature B-cell type acute leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Metastases to bone marrow
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Metastases to lymph nodes
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Metastases to spleen
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Metastatic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Minimal residual disease

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Monocytic leukaemia in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Myeloblastoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Myeloid leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Myeloid leukaemia in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Natural killer-cell leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Natural killer-cell lymphoblastic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Neonatal leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodal marginal zone B-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Nodular lymphocyte predominant Hodgkin lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma metastatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma transformed recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma unspecified histology aggressive
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma unspecified histology aggressive recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma unspecified histology aggressive refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma unspecified histology aggressive stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma unspecified histology aggressive stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin’s lymphoma unspecified histology aggressive stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin's lymphoma unspecified histology aggressive stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin's lymphoma unspecified histology indolent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin's lymphoma unspecified histology indolent stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin's lymphoma unspecified histology indolent stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin's lymphoma unspecified histology indolent stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Non-Hodgkin's lymphoma unspecified histology indolent stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Ocular lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Peripheral T-cell lymphoma unspecified stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Philadelphia positive acute lymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Philadelphia positive chronic myeloid leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasma cell leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasma cell leukaemia in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasma cell myeloma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasma cell myeloma in remission
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasma cell myeloma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasma cell myeloma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasmablastic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Plasmacytoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor B-lymphoblastic lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic leukaemia acute
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Precursor T-lymphoblastic lymphoma/leukaemia stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary breast lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary cardiac lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary effusion lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary gastrointestinal follicular lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Primary mediastinal large B-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Prolymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Richter's syndrome
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Splenic marginal zone lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell chronic lymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell lymphoma stage IV
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell prolymphocytic leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell type acute leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell unclassifiable lymphoma high grade
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		T-cell unclassifiable lymphoma low grade
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Thymic cancer metastatic
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Thymoma malignant
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Thymoma malignant recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Thyroid B-cell lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Transformation to acute myeloid leukaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Triple hit lymphoma
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia recurrent
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia refractory
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia stage I
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia stage II
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia stage III
Malignant tumours	Haematological malignant tumours (SMQ)	NARROW		Waldenstrom’s macroglobulinaemia stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Abdominal wall neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acinar cell carcinoma of pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acinic cell carcinoma of salivary gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acral lentiginous melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acral lentiginous melanoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acral lentiginous melanoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acral lentiginous melanoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Acral lentiginous melanoma stage IV

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma gastric
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma of appendix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma of colon
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma of salivary gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma of the cervix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenocarcinoma pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenoid cystic carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenoid cystic carcinoma of salivary gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous carcinoma of the cervix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous carcinoma of vagina
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adenosquamous cell lung cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adrenal gland cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adrenal gland cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Adrenocortical carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Aesthesioneuroblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Alveolar rhabdomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Alveolar soft part sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Alveolar soft part sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Alveolar soft part sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ameloblastic carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anal squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anaplastic astrocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anaplastic meningioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anaplastic oligodendroglioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Anaplastic thyroid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Angiocentric glioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Angiosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Angiosarcoma metastatic

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Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Angiosarcoma non-metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Angiosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Apocrine breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Appendix cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Appendix cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Astrocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Astrocytoma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Atypical teratoid/rhabdoid tumour of CNS
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Basal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Basal cell carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Basosquamous carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Basosquamous carcinoma of skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct adenosquamous carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bile duct squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Biliary cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Biphasic mesothelioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder adenocarcinoma stage unspecified
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage 0, with cancer in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage 0, without cancer in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage I, with cancer in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage I, without cancer in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder squamous cell carcinoma stage unspecified
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bladder transitional cell carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bone cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bone cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bone giant cell tumour malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bone sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bowen’s disease
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Brain cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Brain neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Brain sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Brain stem glioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast angiosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast angiosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer female
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer male
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast sarcoma metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Breast sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bronchial carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Bronchioloalveolar carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Buschke-Lowenstein's tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		CNS germinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cancer in remission
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cancer with a high tumour mutational burden
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the appendix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the caecum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the duodenum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the gastrointestinal tract
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the liver
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the ovary
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the prostate
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the small bowel
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour of the stomach
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoid tumour pulmonary
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoma ex-pleomorphic adenoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoma in situ of eye
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoma in situ of penis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoma in situ of skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Carcinoma in situ of trachea
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cardiac neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Central nervous system melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Central nervous system neuroblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cervix carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cholangiocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cholangiosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Chondrosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Chondrosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Chondrosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Chordoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Choriocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Choroid melanoma

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Choroid plexus carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Chromophobe renal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ciliary body melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Clear cell carcinoma of cervix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Clear cell endometrial carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Clear cell renal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Clear cell sarcoma of soft tissue
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Clear cell sarcoma of the kidney
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colon cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Colorectal carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Congenital fibrosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Congenital malignant neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Congenital retinoblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Conjunctival melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Craniopharyngioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cystadenocarcinoma ovary
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Cystadenocarcinoma pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Dedifferentiated liposarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Dermatofibrosarcoma protuberans
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Dermatofibrosarcoma protuberans metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Desmoplastic melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Desmoplastic mesothelioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Desmoplastic small round cell tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ductal adenocarcinoma of pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ear neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Eccrine carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Embryonal rhabdomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endocrine neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endometrial stromal sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Endotheliomatosis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ependymoma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Epididymal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Epiglottic cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Epithelioid mesothelioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Epithelioid sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Epithelioid sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Epithelioid sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ewing’s sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ewing’s sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ewing’s sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ewing-like sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		External ear neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extra-osseous Ewing’s sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extra-osseous Ewing’s sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extra-osseous Ewing’s sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary embryonal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary germ cell tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary germ cell tumour mixed
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary germ cell tumour mixed stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary germ cell tumour mixed stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary germ cell tumour mixed stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary malignant teratoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary non-seminoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary non-seminoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary non-seminoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary non-seminoma stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary non-seminoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary seminoma (pure)
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary seminoma (pure) stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary seminoma (pure) stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary seminoma (pure) stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extragonadal primary seminoma (pure) stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extramammary Paget's disease
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraocular retinoblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraskeletal chondrosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraskeletal chondrosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraskeletal myxoid chondrosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraskeletal osteosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraskeletal osteosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Extraskeletal osteosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fallopian tube cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fallopian tube cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fallopian tube cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fallopian tube cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fallopian tube cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fallopian tube cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Familial medullary thyroid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Female reproductive tract carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fibrosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Fibrosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Follicular thyroid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder adenosquamous carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gallbladder squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ganglioglioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ganglioneuroblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer recurrent

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastric sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrinoma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastroenteropancreatic neuroendocrine tumour disease
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrointestinal adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrointestinal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrointestinal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrointestinal carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrointestinal melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrointestinal stromal tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrooesophageal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gastrooesophageal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Genital cancer male
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Genital cancer male in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Genital neoplasm malignant female
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Genitourinary melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Germ cell cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Germ cell cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gestational trophoblastic tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gingival cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glioblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glioblastoma multiforme
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gliomatosis cerebri
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glioneuronal tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Gliosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glomangiopericytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glottis carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Glucagonoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		HER2 mutant non-small cell lung cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		HER2 negative breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		HER2 positive breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		HER2 positive gastric cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		HER2 positive salivary gland cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Haemangiopericytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Haemangiopericytoma of meninges
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Head and neck cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Head and neck cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Head and neck cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Head and neck cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Head and neck cancer stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Head and neck cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic angiosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatic cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatobiliary cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatobiliary cancer in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatoblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatoblastoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hepatocellular carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hereditary leiomyomatosis renal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hereditary papillary renal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hidradenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Homologous recombination deficiency positive advanced ovarian cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hormone receptor negative HER2 positive breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hormone receptor positive HER2 negative breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hormone receptor positive breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hormone refractory breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hormone-dependent prostate cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hormone-refractory prostate cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Huerthle cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Hypopharyngeal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Inflammatory carcinoma of breast recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Inflammatory carcinoma of breast stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Inflammatory carcinoma of breast stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Inflammatory carcinoma of the breast

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Inflammatory malignant fibrous histiocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Inflammatory myofibroblastic tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intestinal adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intestinal metastasis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intracranial germ cell tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intracranial meningioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intraductal papillary breast neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intraductal papillary-mucinous carcinoma of pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intraductal proliferative breast lesion
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Intraocular melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Invasive breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Invasive ductal breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Invasive lobular breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Invasive papillary breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Iris melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Kaposi’s sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Kaposi’s sarcoma AIDS related
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Kaposi’s sarcoma classical type
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Keratinising squamous cell carcinoma of nasopharynx
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Keratoacanthoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Langerhans cell sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Large cell lung cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Laryngeal squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Leiomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Leiomyosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Leiomyosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lentigo maligna
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lentigo maligna recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lentigo maligna stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lentigo maligna stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lentigo maligna stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lentigo maligna stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Leydig cell tumour of the testis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Linitis plastica
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip and/or oral cavity cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip neoplasm malignant stage unspecified
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lip squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Liposarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Liposarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Liposarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lobular breast carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung adenocarcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung carcinoma cell type unspecified recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung carcinoma cell type unspecified stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung carcinoma cell type unspecified stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung carcinoma cell type unspecified stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung carcinoma cell type unspecified stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung carcinoma cell type unspecified stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung infiltration malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma stage II

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Lung squamous cell carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant anorectal neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant blue naevus
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant connective tissue neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant cranial nerve neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant fibrous histiocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant fibrous histiocytoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant fibrous histiocytoma of bone
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant fibrous histiocytoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant genitourinary tract neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant giant cell fibrous histiocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant glioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant haemangiopericytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant haemangiopericytoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant haemangiopericytoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant hydatidiform mole
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant joint neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant mediastinal neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma of eyelid
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma of sites other than skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant melanoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant meningioma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant mesenchymoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant mesenchymoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant mesenchymoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant mesenteric neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant middle ear neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant muscle neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of ampulla of Vater
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of choroid
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of conjunctiva
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of cornea
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of eye
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of eyelid
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of islets of Langerhans
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of lacrimal duct

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of lacrimal gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of orbit
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of paraurethral glands
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of placenta
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of pleura
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of pleura metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of renal pelvis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of retina
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of seminal vesicle
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of spermatic cord
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of spinal cord
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of thorax
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of unknown primary site
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm of uterine adnexa
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant neoplasm papilla of Vater
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant nervous system neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant nipple neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant nipple neoplasm female
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant nipple neoplasm male
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant oligodendroglioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant ovarian cyst
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant palate neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant pericardial neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant peritoneal neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant pituitary tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant polyp
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant respiratory tract neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant sweat gland neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant transformation
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Malignant urinary tract neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Marjolin's ulcer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Maternal cancer in pregnancy
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Medullary carcinoma of breast
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Medullary thyroid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Medulloblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Medulloblastoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Melanoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Meningioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mesothelioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mesothelioma malignant recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metaplastic breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to Eustachian tube
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to abdominal cavity
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to abdominal wall

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to adrenals
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to biliary tract
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to bladder
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to bone
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to breast
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to central nervous system
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to chest wall
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to diaphragm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to eye
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to fallopian tube
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to gallbladder
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to gastrointestinal tract
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to heart
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to kidney
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to larynx
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to liver
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to lung
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to meninges
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to mouth
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to muscle
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to nasal sinuses
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to neck
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to nervous system
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to oesophagus
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to ovary
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to pelvis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to penis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to perineum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to peripheral nervous system
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to peripheral vascular system
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to peritoneum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to pharynx
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to pituitary gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to placenta
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to pleura
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to prostate
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to rectum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to reproductive organ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to retroperitoneum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to salivary gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to soft tissue
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to spinal cord
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to spine
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to stomach

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to testicle
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to the mediastinum
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to the respiratory system
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to thorax
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to thyroid
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to tonsils
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to trachea
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to urinary tract
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to uterus
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastases to vagina
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastasis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic bronchial carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic carcinoid tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic carcinoma of the bladder
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic choriocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic gastric cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic glioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic glucagonoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic malignant melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic nervous system neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic ocular melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic renal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic salivary gland cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Metastatic uterine cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Microsatellite instability cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mismatch repair cancer syndrome
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mixed adenoneuroendocrine carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mixed hepatocellular cholangiocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mixed-type liposarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mucinous adenocarcinoma of appendix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mucinous breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mucinous cystadenocarcinoma ovary
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mucinous endometrial carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mucoepidermoid carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Mucoepidermoid carcinoma of salivary gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Musculoskeletal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Myxofibrosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Myxoid liposarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		NUT midline carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Naevoid melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasal cavity cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasal sinus cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nasopharyngeal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neonatal neuroblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nephroblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroblastoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine breast tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine carcinoma of prostate
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine carcinoma of the bladder
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine carcinoma of the skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine tumour of the lung
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neuroendocrine tumour of the lung metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neurofibrosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neurofibrosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Neurofibrosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nodular melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-renal cell carcinoma of kidney
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage IIIA
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage IIIB
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Non-small cell lung cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nongerminomatous germ cell tumour of the CNS
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Nonkeratinising carcinoma of nasopharynx
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ocular cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ocular haemangiopericytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenocarcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal adenosquamous carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oesophageal squamous cell carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oligoastrocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oligodendroglioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Optic glioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oral cavity cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal lymphoepithelioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Oropharyngeal squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Osteosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Osteosarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Osteosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Otic cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian clear cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian dysgerminoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian dysgerminoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian dysgerminoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian dysgerminoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian dysgerminoma stage unspecified
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian embryonal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian endometrioid carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian epithelial cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell choriocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell choriocarcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell choriocarcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell choriocarcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell choriocarcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell embryonal carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell embryonal carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell embryonal carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell embryonal carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell endodermal sinus tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell endodermal sinus tumour stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell endodermal sinus tumour stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell endodermal sinus tumour stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell endodermal sinus tumour stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell polyembryoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell polyembryoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell polyembryoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell polyembryoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell polyembryoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell teratoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell teratoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell teratoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell teratoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell teratoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian germ cell tumour mixed
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian granulosa-theca cell tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian low malignant potential tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ovarian stromal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paget's disease of nipple
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paget's disease of penis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paget's disease of the vulva
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancoast's tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic neuroendocrine tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic neuroendocrine tumour metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatic sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pancreatoblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Papillary renal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Papillary serous endometrial carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Papillary thyroid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paraganglion neoplasm malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Paranasal sinus and nasal cavity malignant neoplasm stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Parathyroid tumour malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penile cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penile squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penis carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penis carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penis carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penis carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penis carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Penis carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pericardial mesothelioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pericardial mesothelioma malignant recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peripheral neuroepithelioma of bone
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peripheral neuroepithelioma of bone metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peripheral neuroepithelioma of bone recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peripheral neuroepithelioma of soft tissue
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peripheral primitive neuroectodermal bone tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peripheral primitive neuroectodermal tumour of soft tissue
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peritoneal carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peritoneal mesothelioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peritoneal mesothelioma malignant recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Peritoneal sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Phaeochromocytoma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pharyngeal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pilomatrix carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pineal germinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pineal parenchymal neoplasm malignant

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pinealoblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pituitary cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pituitary neoplasm malignant recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleomorphic leiomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleomorphic liposarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleomorphic malignant fibrous histiocytoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleural mesothelioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleural mesothelioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleural mesothelioma malignant recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleural sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pleuropulmonary blastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Poorly differentiated thyroid carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Porocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Postcricoid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Primary pulmonary melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Primitive neuroectodermal tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Primitive neuroectodermal tumour metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Prostate cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Pseudosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Queyrat erythroplasia
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rectosigmoid cancer stage IV

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Recurrent N-ras mutation-positive colorectal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Recurrent cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Refractory cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cell carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cell carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cell carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cell carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Renal cell carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Respiratory tract carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Retinal melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Retinoblastoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Retroperitoneal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Retroperitoneal neoplasm metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rhabdoid tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rhabdoid tumour of the kidney
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rhabdomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Rhabdomyosarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Round cell liposarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Salivary gland cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcoma of skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcoma uterus
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcomatoid carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcomatoid carcinoma of the lung
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcomatoid mesothelioma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sarcomatosis
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Scrotal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sebaceous carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Second primary malignancy
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Seminoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Serous cystadenocarcinoma ovary
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Signet-ring cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Sinus cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Skin angiosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Skin cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Skin cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Skin squamous cell carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Skin squamous cell carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell carcinoma of the cervix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell lung cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell lung cancer extensive stage
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell lung cancer limited stage
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell lung cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small cell lung cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Small intestine leiomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Soft tissue sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Solid pseudopapillary tumour of the pancreas
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Spermatocytic seminoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Spinal meningioma malignant
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Spindle cell sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of head and neck
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of lung
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of pharynx
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of skin
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the cervix
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the hypopharynx
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the oral cavity
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the parotid gland
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the tongue
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the vagina

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous cell carcinoma of the vulva
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Squamous endometrial carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Stewart-Treves syndrome
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Superficial spreading melanoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Superficial spreading melanoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Superficial spreading melanoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Superficial spreading melanoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Superficial spreading melanoma stage unspecified
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Synovial sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Synovial sarcoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Synovial sarcoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular choriocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular choriocarcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular choriocarcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular choriocarcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular choriocarcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular embryonal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular embryonal carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular embryonal carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular embryonal carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular germ cell cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular germ cell cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular germ cell tumour mixed
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular germ cell tumour mixed stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular germ cell tumour mixed stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular germ cell tumour mixed stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular leiomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular malignant teratoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular malignant teratoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular malignant teratoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular malignant teratoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular seminoma (pure)
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular seminoma (pure) stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular seminoma (pure) stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular seminoma (pure) stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular yolk sac tumour
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular yolk sac tumour stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular yolk sac tumour stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testicular yolk sac tumour stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testis cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Testis cancer recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Throat cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Thyroid cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue carcinoma stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue carcinoma stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue carcinoma stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue carcinoma stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue carcinoma stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tongue neoplasm malignant stage unspecified
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tonsil cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tonsil cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tracheal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell cancer of renal pelvis and ureter metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell cancer of the renal pelvis and ureter
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell cancer of the renal pelvis and ureter localised
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell cancer of the renal pelvis and ureter recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell cancer of the renal pelvis and ureter regional
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell carcinoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell carcinoma recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Transitional cell carcinoma urethra
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Trichoblastic carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Triple negative breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Triple positive breast cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tubular breast carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Tumour budding
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Undifferentiated carcinoma of colon
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Undifferentiated nasopharyngeal carcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Undifferentiated sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ureteric cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ureteric cancer local

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ureteric cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ureteric cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Ureteric cancer regional
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Urethral cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Urethral cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Urethral cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Urethral melanoma metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Urinary bladder sarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Urinary tract carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Uterine cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Uterine carcinoma in situ
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Uterine leiomyosarcoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Uveal melanoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer stage IVA
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vaginal cancer stage IVB
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer metastatic
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer recurrent
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer stage 0
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer stage I
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer stage II
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer stage III
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulval cancer stage IV
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulvar adenocarcinoma
Malignant tumours	Non-haematological malignant tumours (SMQ)	NARROW		Vulvar basal cell carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Atypical fibroxanthoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Basal cell carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Basal cell carcinoma metastatic
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Basosquamous carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Basosquamous carcinoma of skin

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Blastic plasmacytoid dendritic cell neoplasia
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Bowen's disease
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Carcinoma in situ of penis
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Carcinoma in situ of skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma refractory
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Cutaneous lymphoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Dermatofibrosarcoma protuberans
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Dermatofibrosarcoma protuberans metastatic
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Desmoplastic melanoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Eccrine carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Electron radiation therapy to skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Extramammary Paget's disease
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Gamma radiation therapy to skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Hidradenocarcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Kaposi's sarcoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Kaposi's sarcoma AIDS related
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Kaposi's sarcoma classical type
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Keratoacanthoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Lentigo maligna
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Lentigo maligna recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Lentigo maligna stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Lentigo maligna stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Lentigo maligna stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Lentigo maligna stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant blue naevus
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma in situ
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma of eyelid
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Malignant sweat gland neoplasm
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Marjolin's ulcer
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Melanoma recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Metastatic malignant melanoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Metastatic squamous cell carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Naevoid melanoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Neuroendocrine carcinoma of the skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Nodular melanoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Paget's disease of penis
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penile cancer
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penile squamous cell carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma metastatic
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified refractory
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Photon radiation therapy to skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Pilomatrix carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Queyrat erythroplasia
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Sarcoma of skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Sebaceous carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Skin angiosarcoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Skin cancer
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Skin cancer metastatic
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Skin squamous cell carcinoma metastatic
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Skin squamous cell carcinoma recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Squamous cell carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of skin
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the vulva
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage unspecified
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Trichoblastic carcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer recurrent
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage 0
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage I
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage II
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage III
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage IV
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulvar adenocarcinoma
Malignant skin tumours	Skin malignant tumours (SMQ)	BROAD		Vulvectomy
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Acral lentiginous melanoma
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Acral lentiginous melanoma stage I
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Acral lentiginous melanoma stage II
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Acral lentiginous melanoma stage III
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Acral lentiginous melanoma stage IV
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Desmoplastic melanoma
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Lentigo maligna
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Lentigo maligna recurrent
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Lentigo maligna stage I
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Lentigo maligna stage II
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Lentigo maligna stage III
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Lentigo maligna stage IV
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant blue naevus
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant melanoma
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant melanoma in situ
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant melanoma stage I
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant melanoma stage II
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant melanoma stage III
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Malignant melanoma stage IV
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Melanoma recurrent
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Metastatic malignant melanoma
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Naevoid melanoma
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Nodular melanoma
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Superficial spreading melanoma stage I
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Superficial spreading melanoma stage II
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Superficial spreading melanoma stage III
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Superficial spreading melanoma stage IV
Skin melanomas	Skin melanomas (excl ocular) (HLT)			Superficial spreading melanoma stage unspecified
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Atypical fibroxanthoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Basal cell carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Basal cell carcinoma metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Basosquamous carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Basosquamous carcinoma of skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Blastic plasmacytoid dendritic cell neoplasia
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Bowen's disease
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Carcinoma in situ of penis
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Carcinoma in situ of skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma recurrent
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma refractory
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage I
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage II
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage III
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous T-cell lymphoma stage IV
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Cutaneous lymphoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Dermatofibrosarcoma protuberans
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Dermatofibrosarcoma protuberans metastatic
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Eccrine carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Electron radiation therapy to skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Extramammary Paget's disease
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Gamma radiation therapy to skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Hidradenocarcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Kaposi's sarcoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Kaposi's sarcoma AIDS related

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Kaposi's sarcoma classical type
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Keratoacanthoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Malignant melanoma of eyelid
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Malignant sweat gland neoplasm
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Marjolin's ulcer
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Metastatic squamous cell carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Neuroendocrine carcinoma of the skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Paget's disease of penis
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penile cancer
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penile squamous cell carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma metastatic
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma recurrent
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage I
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage II
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage III
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Penis carcinoma stage IV
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified recurrent
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified refractory
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage I
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage II
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage III
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Peripheral T-cell lymphoma unspecified stage IV

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Photon radiation therapy to skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Pilomatrix carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Queyrat erythroplasia
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Sarcoma of skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Sebaceous carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Skin angiosarcoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Skin cancer
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Skin cancer metastatic
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Skin squamous cell carcinoma metastatic
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Skin squamous cell carcinoma recurrent
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Squamous cell carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of skin
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the vulva
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Trichoblastic carcinoma
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer metastatic
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer recurrent
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage 0
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage I
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage II
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage III
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulval cancer stage IV
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulvar adenocarcinoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Non-melanoma skin cancer (NMSC)	Skin malignant tumours (SMQ)	BROAD		Vulvectomy
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		5q minus syndrome
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Abdominal wall neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acinar cell carcinoma of pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acinic cell carcinoma of salivary gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acral lentiginous melanoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute bilineal leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute biphenotypic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute erythroid leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute leukaemia in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute lymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute lymphocytic leukaemia (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute lymphocytic leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute lymphocytic leukaemia refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute megakaryocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute megakaryocytic leukaemia (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute monocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute monocytic leukaemia (in remission)

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute myeloid leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute myeloid leukaemia (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute myeloid leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute myeloid leukaemia refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute myelomonocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute promyelocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Acute undifferentiated leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma gastric
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma of appendix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma of colon
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma of salivary gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma of the cervix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenocarcinoma pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenoid cystic carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenoid cystic carcinoma of salivary gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous carcinoma of the cervix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous carcinoma of vagina
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer stage 0

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adenosquamous cell lung cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adrenal gland cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adrenal gland cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adrenocortical carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Adult T-cell lymphoma/leukaemia stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Aesthesioneuroblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Aleukaemic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Alveolar rhabdomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Alveolar soft part sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Alveolar soft part sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Alveolar soft part sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ameloblastic carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anal squamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic astrocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large cell lymphoma T- and null-cell types stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic large-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic meningioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic oligodendroglioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Anaplastic thyroid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric glioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiocentric lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angioimmunoblastic T-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiosarcoma non-metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Angiosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Apocrine breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Appendix cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Appendix cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Astrocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Astrocytoma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Atypical teratoid/rhabdoid tumour of CNS
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B precursor type acute leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell prolymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell small lymphocytic lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell type acute leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell unclassifiable lymphoma high grade
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		B-cell unclassifiable lymphoma low grade
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct adenosquamous carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer stage II

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bile duct squamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Biliary cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Biphasic mesothelioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder adenocarcinoma stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage 0, with cancer in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage 0, without cancer in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage I, with cancer in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage I, without cancer in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma stage 0

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder squamous cell carcinoma stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bladder transitional cell carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Blast cell crisis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Blast crisis in myelogenous leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bone cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bone cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bone giant cell tumour malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bone marrow leukaemic cell infiltration
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bone marrow tumour cell infiltration
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bone sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Brain cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Brain neoplasm malignant

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Brain sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Brain stem glioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast angiosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast angiosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer female
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer male
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast implant-associated anaplastic large cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Breast sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bronchial carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Bronchioloalveolar carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt’s leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt’s lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt’s lymphoma recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt's lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt's lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt's lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt's lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Burkitt's lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Buschke-Lowenstein's tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		CNS germinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cancer in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cancer with a high tumour mutational burden
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the appendix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the caecum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the duodenum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the gastrointestinal tract
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the liver
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the ovary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the prostate
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the small bowel
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour of the stomach
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoid tumour pulmonary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoma ex-pleomorphic adenoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoma in situ

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoma in situ of eye
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Carcinoma in situ of trachea
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cardiac neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Central nervous system leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Central nervous system lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Central nervous system melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Central nervous system neuroblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cervix carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chloroma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chloroma (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cholangiocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cholangiosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chondrosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chondrosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chondrosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chordoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Choriocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Choroid melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Choroid plexus carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chromophobe renal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic eosinophilic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic leukaemia in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia stage 1
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia stage 2
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia stage 3
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia stage 4
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic lymphocytic leukaemia transformation
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myeloid leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myeloid leukaemia (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myeloid leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myeloid leukaemia transformation
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myelomonocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myelomonocytic leukaemia (in remission)

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Chronic myelomonocytic leukaemia with N-ras gene mutation
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ciliary body melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Clear cell carcinoma of cervix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Clear cell endometrial carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Clear cell renal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Clear cell sarcoma of soft tissue
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Clear cell sarcoma of the kidney
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colon cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal cancer stage IV

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Colorectal carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Composite lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Congenital fibrosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Congenital malignant neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Congenital retinoblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Conjunctival melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Craniopharyngioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cutaneous B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cystadenocarcinoma ovary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Cystadenocarcinoma pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Dedifferentiated liposarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Desmoplastic melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Desmoplastic mesothelioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Desmoplastic small round cell tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Diffuse large B-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Disseminated large cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Double hit lymphoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ductal adenocarcinoma of pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ear neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Embryonal rhabdomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endocrine neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endometrial stromal sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Endotheliomatosis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Enteropathy-associated T-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Eosinophilic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ependymoma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epididymal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epiglottic cancer

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epithelioid mesothelioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epithelioid sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epithelioid sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epithelioid sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Epstein-Barr virus associated lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Erythraemic myelosis (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ewing's sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ewing's sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ewing's sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ewing-like sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		External ear neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extra-osseous Ewing's sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extra-osseous Ewing's sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extra-osseous Ewing's sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary embryonal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary germ cell tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary germ cell tumour mixed
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary germ cell tumour mixed stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary germ cell tumour mixed stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary germ cell tumour mixed stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary malignant teratoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary non-seminoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary non-seminoma stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary non-seminoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary non-seminoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary non-seminoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary seminoma (pure)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary seminoma (pure) stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary seminoma (pure) stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary seminoma (pure) stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extragonadal primary seminoma (pure) stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (BALT type)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type) recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type) refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type) stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type) stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type) stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extranodal marginal zone B-cell lymphoma (MALT type) stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraocular retinoblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraskeletal chondrosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraskeletal chondrosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraskeletal myxoid chondrosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraskeletal osteosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraskeletal osteosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Extraskeletal osteosarcoma recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fallopian tube cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fallopian tube cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fallopian tube cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fallopian tube cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fallopian tube cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fallopian tube cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Familial medullary thyroid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Female reproductive tract carcinoma in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fibrosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Fibrosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma diffuse small cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicle centre lymphoma, follicular grade I, II, III stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular dendritic cell sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Follicular thyroid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder adenosquamous carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gallbladder squamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ganglioglioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ganglioneuroblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastric sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrinoma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastroenteropancreatic neuroendocrine tumour disease
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal carcinoma in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrointestinal stromal tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrooesophageal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gastrooesophageal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Genital cancer male
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Genital cancer male in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Genital neoplasm malignant female
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Genitourinary melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Germ cell cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Germ cell cancer metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gestational trophoblastic tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gingival cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glioblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glioblastoma multiforme
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gliomatosis cerebri
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glioneuronal tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Gliosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glomangiopericytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glottis carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Glucagonoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Grey zone lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		HER2 mutant non-small cell lung cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		HER2 negative breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		HER2 positive breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		HER2 positive gastric cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		HER2 positive salivary gland cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Haemangiopericytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Haemangiopericytoma of meninges
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Haematological malignancy
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hairy cell leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hairy cell leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Head and neck cancer

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Head and neck cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Head and neck cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Head and neck cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Head and neck cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Head and neck cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic angiosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatic cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatobiliary cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatobiliary cancer in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatoblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatoblastoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatocellular carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hepatosplenic T-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hereditary leiomyomatosis renal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hereditary papillary renal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High grade B-cell lymphoma Burkitt-like lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		High-grade B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Histiocytic medullary reticulosis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Histiocytic sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion stage I site unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion stage I subdiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion stage I supradiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion stage II site unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion stage II subdiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion stage II supradiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion type recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion type refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion type stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion type stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte depletion type stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte predominance stage I site unspec
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte predominance stage I subdiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin’s disease lymphocyte predominance stage I supradiaphragm

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance stage II site unspec
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance stage II subdiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance stage II supradiaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance type recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance type refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance type stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance type stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease lymphocyte predominance type stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage I site unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage I subdiaphragmatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage I supradiaphragmatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage II subdiaphragmatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage II supradiaphragmatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease mixed cellularity stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis stage II

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease nodular sclerosis stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hodgkin's disease unclassifiable
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Homologous recombination deficiency positive advanced ovarian cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hormone receptor negative HER2 positive breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hormone receptor positive HER2 negative breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hormone receptor positive breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hormone refractory breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hormone-dependent prostate cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hormone-refractory prostate cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Huerthle cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Hypopharyngeal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Immune reconstitution inflammatory syndrome associated Kaposi's sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Immunoblastic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Inflammatory carcinoma of breast recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Inflammatory carcinoma of breast stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Inflammatory carcinoma of breast stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Inflammatory carcinoma of the breast
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Inflammatory malignant fibrous histiocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Inflammatory myofibroblastic tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal T-cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal T-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal T-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal T-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal T-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal T-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intestinal metastasis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intracranial germ cell tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intracranial meningioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intraductal papillary breast neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intraductal papillary-mucinous carcinoma of pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intraductal proliferative breast lesion
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Intraocular melanoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Invasive breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Invasive ductal breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Invasive lobular breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Invasive papillary breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Iris melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Juvenile chronic myelomonocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Keratinising squamous cell carcinoma of nasopharynx
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Langerhans cell sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Large cell lung cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer stage III

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Laryngeal squamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leiomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leiomyosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leiomyosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lentigo maligna
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lentigo maligna recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lentigo maligna stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lentigo maligna stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lentigo maligna stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lentigo maligna stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leptomeningeal myelomatosis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia basophilic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia cutis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia granulocytic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia monocytic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic cardiac infiltration
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration extramedullary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration gingiva

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration hepatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration ovary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration pulmonary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic infiltration renal
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leukaemic retinopathy
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Leydig cell tumour of the testis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lineage switch leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Linitis plastica
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip and/or oral cavity cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip neoplasm malignant stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lip squamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Liposarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Liposarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Liposarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lobular breast carcinoma in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung adenocarcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung carcinoma cell type unspecified recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung carcinoma cell type unspecified stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung carcinoma cell type unspecified stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung carcinoma cell type unspecified stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung carcinoma cell type unspecified stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung carcinoma cell type unspecified stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung infiltration malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lung squamous cell carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphangiosarcoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphangiosis carcinomatosa
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphocytic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoid leukaemia (in remission)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoma AIDS related
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoma transformation
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Lymphoplasmacytoid lymphoma/immunocytoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant anorectal neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant blue naevus
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant connective tissue neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant cranial nerve neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant fibrous histiocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant fibrous histiocytoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant fibrous histiocytoma of bone
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant fibrous histiocytoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant genitourinary tract neoplasm

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant giant cell fibrous histiocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant glioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant haemangiopericytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant haemangiopericytoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant haemangiopericytoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant histiocytosis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant hydatidiform mole
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant joint neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant lymphoid neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant lymphoma unclassifiable high grade
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant lymphoma unclassifiable low grade
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant mast cell neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant mediastinal neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma of sites other than skin
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant melanoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant meningioma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant mesenchymoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant mesenchymoma metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant mesenchymoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant mesenteric neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant middle ear neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant muscle neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of ampulla of Vater
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of choroid
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of conjunctiva
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of cornea
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of eye
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of eyelid
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of islets of Langerhans
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of lacrimal duct
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of lacrimal gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of orbit
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of paraurethral glands
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of placenta
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of pleura
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of pleura metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of renal pelvis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of retina
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of seminal vesicle
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of spermatic cord
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of spinal cord

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of thorax
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of thymus
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of unknown primary site
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm of uterine adnexa
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant neoplasm papilla of Vater
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant nervous system neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant nipple neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant nipple neoplasm female
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant nipple neoplasm male
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant oligodendroglioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant ovarian cyst
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant palate neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant pericardial neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant peritoneal neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant pituitary tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant polyp
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant respiratory tract neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant splenic neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant transformation
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Malignant urinary tract neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma refractory

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mantle cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Marginal zone lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mastocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Maternal cancer in pregnancy
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mature B-cell type acute leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Medullary carcinoma of breast
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Medullary thyroid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Medulloblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Medulloblastoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Melanoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Meningioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mesothelioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mesothelioma malignant recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metaplastic breast carcinoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to Eustachian tube
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to abdominal cavity
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to abdominal wall
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to adrenals
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to biliary tract
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to bladder
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to bone
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to bone marrow
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to breast
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to central nervous system
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to chest wall
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to diaphragm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to eye
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to fallopian tube
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to gallbladder
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to gastrointestinal tract
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to heart
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to kidney
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to larynx
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to liver
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to lung
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to lymph nodes
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to meninges

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to mouth
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to muscle
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to nasal sinuses
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to neck
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to nervous system
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to oesophagus
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to ovary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to pelvis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to penis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to perineum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to peripheral nervous system
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to peripheral vascular system
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to peritoneum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to pharynx
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to pituitary gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to placenta
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to pleura
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to prostate
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to rectum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to reproductive organ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to retroperitoneum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to salivary gland

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to skin
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to soft tissue
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to spinal cord
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to spine
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to spleen
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to stomach
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to testicle
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to the mediastinum
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to the respiratory system
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to thorax
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to thyroid
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to tonsils
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to trachea
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to urinary tract
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to uterus
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastases to vagina
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastasis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic bronchial carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic carcinoid tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic carcinoma of the bladder
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic choriocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic gastric cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic glioma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic glucagonoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic malignant melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic nervous system neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic ocular melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic renal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic salivary gland cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Metastatic uterine cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Microsatellite instability cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Minimal residual disease
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mismatch repair cancer syndrome
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mixed adenoneuroendocrine carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mixed hepatocellular cholangiocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mixed-type liposarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Monocytic leukaemia in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mucinous adenocarcinoma of appendix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mucinous breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mucinous cystadenocarcinoma ovary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mucinous endometrial carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mucoepidermoid carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Mucoepidermoid carcinoma of salivary gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Musculoskeletal cancer

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Myeloblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Myeloid leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Myeloid leukaemia in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Myxofibrosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Myxoid liposarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		NUT midline carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Naevoid melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasal cavity cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasal sinus cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nasopharyngeal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Natural killer-cell leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Natural killer-cell lymphoblastic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neonatal leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neonatal neuroblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nephroblastoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroblastoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine breast tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine carcinoma of prostate
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine carcinoma of the bladder
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine tumour of the lung
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neuroendocrine tumour of the lung metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neurofibrosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neurofibrosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Neurofibrosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodal marginal zone B-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodular lymphocyte predominant Hodgkin lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nodular melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin’s lymphoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma transformed recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology aggressive stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology indolent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology indolent stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology indolent stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology indolent stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-Hodgkin's lymphoma unspecified histology indolent stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-renal cell carcinoma of kidney
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage IIIA
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage IIIB
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Non-small cell lung cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nongerminomatous germ cell tumour of the CNS
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Nonkeratinising carcinoma of nasopharynx
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ocular cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ocular haemangiopericytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ocular lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenocarcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal adenosquamous carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal carcinoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oesophageal squamous cell carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oligoastrocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oligodendroglioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Optic glioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oral cavity cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal lymphoepithelioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Oropharyngeal squamous cell carcinoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Osteosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Osteosarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Osteosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Otic cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian clear cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian dysgerminoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian dysgerminoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian dysgerminoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian dysgerminoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian dysgerminoma stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian embryonal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian endometrioid carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian epithelial cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell choriocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell choriocarcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell choriocarcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell choriocarcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell choriocarcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell embryonal carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell embryonal carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell embryonal carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell embryonal carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell endodermal sinus tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell endodermal sinus tumour stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell endodermal sinus tumour stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell endodermal sinus tumour stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell endodermal sinus tumour stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell polyembryoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell polyembryoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell polyembryoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell polyembryoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell polyembryoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell teratoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell teratoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell teratoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell teratoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell teratoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian germ cell tumour mixed
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian granulosa-theca cell tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian low malignant potential tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ovarian stromal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paget’s disease of nipple
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paget’s disease of the vulva
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancoast’s tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma stage II

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic neuroendocrine tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic neuroendocrine tumour metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatic sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pancreatoblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Papillary renal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Papillary serous endometrial carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Papillary thyroid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paraganglion neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Paranasal sinus and nasal cavity malignant neoplasm stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Parathyroid tumour malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pericardial mesothelioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pericardial mesothelioma malignant recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peripheral neuroepithelioma of bone
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peripheral neuroepithelioma of bone metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peripheral neuroepithelioma of bone recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peripheral neuroepithelioma of soft tissue
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peripheral primitive neuroectodermal bone tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peripheral primitive neuroectodermal tumour of soft tissue
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peritoneal carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peritoneal mesothelioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peritoneal mesothelioma malignant recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Peritoneal sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Phaeochromocytoma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pharyngeal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Philadelphia positive acute lymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Philadelphia positive chronic myeloid leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pineal germinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pineal parenchymal neoplasm malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pinealoblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pituitary cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pituitary neoplasm malignant recurrent

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasma cell leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasma cell leukaemia in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasma cell myeloma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasma cell myeloma in remission
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasma cell myeloma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasma cell myeloma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasmablastic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Plasmacytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleomorphic leiomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleomorphic liposarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleomorphic malignant fibrous histiocytoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleural mesothelioma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleural mesothelioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleural mesothelioma malignant recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleural sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pleuropulmonary blastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Poorly differentiated thyroid carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Porocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Postcricoid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma stage I

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor B-lymphoblastic lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic leukaemia acute
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Precursor T-lymphoblastic lymphoma/leukaemia stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary breast lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary cardiac lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary effusion lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary gastrointestinal follicular lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary mediastinal large B-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primary pulmonary melanoma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primitive neuroectodermal tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Primitive neuroectodermal tumour metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prolymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Prostate cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Pseudosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rectosigmoid cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Recurrent N-ras mutation-positive colorectal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Recurrent cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Refractory cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cell carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cell carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cell carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cell carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Renal cell carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Respiratory tract carcinoma in situ

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Retinal melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Retinoblastoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Retroperitoneal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Retroperitoneal neoplasm metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rhabdoid tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rhabdoid tumour of the kidney
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rhabdomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Rhabdomyosarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Richter's syndrome
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Round cell liposarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Salivary gland cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcoma uterus
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcomatoid carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcomatoid carcinoma of the lung
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcomatoid mesothelioma

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sarcomatosis
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Scrotal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Second primary malignancy
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Seminoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Serous cystadenocarcinoma ovary
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Signet-ring cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Sinus cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell carcinoma of the cervix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell lung cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell lung cancer extensive stage
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell lung cancer limited stage
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell lung cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small cell lung cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine carcinoma stage IV

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Small intestine leiomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Soft tissue sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Solid pseudopapillary tumour of the pancreas
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Spermatocytic seminoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Spinal meningioma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Spindle cell sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Splenic marginal zone lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of head and neck
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of lung
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of pharynx
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the cervix
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the hypopharynx
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the oral cavity
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the parotid gland
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the tongue
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous cell carcinoma of the vagina

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Squamous endometrial carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Stewart-Treves syndrome
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Superficial spreading melanoma stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Synovial sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Synovial sarcoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Synovial sarcoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell chronic lymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell lymphoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell prolymphocytic leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell type acute leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell unclassifiable lymphoma high grade
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		T-cell unclassifiable lymphoma low grade
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular cancer metastatic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular choriocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular choriocarcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular choriocarcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular choriocarcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular choriocarcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular embryonal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular embryonal carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular embryonal carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular embryonal carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular germ cell cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular germ cell cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular germ cell tumour mixed
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular germ cell tumour mixed stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular germ cell tumour mixed stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular germ cell tumour mixed stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular leiomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular malignant teratoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular malignant teratoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular malignant teratoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular malignant teratoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular seminoma (pure)
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular seminoma (pure) stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular seminoma (pure) stage II

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular seminoma (pure) stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular yolk sac tumour
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular yolk sac tumour stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular yolk sac tumour stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testicular yolk sac tumour stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testis cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Testis cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Throat cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thymic cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thymoma malignant
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thymoma malignant recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid B-cell lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer stage 0
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Thyroid cancer stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue carcinoma stage 0

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue carcinoma stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue carcinoma stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue carcinoma stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue carcinoma stage IV
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tongue neoplasm malignant stage unspecified
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tonsil cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tonsil cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tracheal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transformation to acute myeloid leukaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell cancer of renal pelvis and ureter metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell cancer of the renal pelvis and ureter
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell cancer of the renal pelvis and ureter localised
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell cancer of the renal pelvis and ureter recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell cancer of the renal pelvis and ureter regional
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell carcinoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell carcinoma recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Transitional cell carcinoma urethra
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Triple hit lymphoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Triple negative breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Triple positive breast cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tubular breast carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Tumour budding

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Undifferentiated carcinoma of colon
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Undifferentiated nasopharyngeal carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Undifferentiated sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ureteric cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ureteric cancer local
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ureteric cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ureteric cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Ureteric cancer regional
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Urethral cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Urethral cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Urethral cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Urethral melanoma metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Urinary bladder sarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Urinary tract carcinoma in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Uterine cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Uterine carcinoma in situ
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Uterine leiomyosarcoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Uveal melanoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal adenocarcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer metastatic
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer stage 0

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer stage IVA
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vaginal cancer stage IVB
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Vulvar basal cell carcinoma
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia recurrent
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia refractory
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia stage I
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia stage II
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia stage III
Malignancies excluding NMSC	Malignant tumours (SMQ)	BROAD		Waldenstrom's macroglobulinaemia stage IV
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Acute myocardial infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Basal ganglia infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Basal ganglia stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Benedikt's syndrome
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Brain stem infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Brain stem stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cardiac death
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebellar infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebellar stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebral infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebral infarction foetal
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebral microinfarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebral septic infarct
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Cerebrovascular accident
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Claude's syndrome
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Embolic cerebellar infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Embolic cerebral infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Embolic stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Haemorrhagic cerebral infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Haemorrhagic stroke

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Haemorrhagic transformation stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Inner ear infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Internal capsule infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Ischaemic cerebral infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Ischaemic stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Kounis syndrome
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Lacunar infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Lacunar stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Migrainous infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Myocardial infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Myocardial necrosis
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Papillary muscle infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Perinatal stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Periprocedural myocardial infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Pituitary apoplexy
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Post procedural myocardial infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Post procedural stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Precerebral artery embolism
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Precerebral artery thrombosis
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Silent myocardial infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Spinal cord infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Spinal stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Stroke in evolution
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Sudden cardiac death
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Sudden death
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Thalamic infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Thrombotic cerebral infarction
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Thrombotic stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Vertebrobasilar stroke
3-point MACE	3-Point MACE Part 1/2 (BIcMQ)	NARROW		Weber's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Abdominal strangulated hernia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Abnormal precordial movement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Accelerated hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Accelerated idioventricular rhythm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Accessory cardiac pathway
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Achenbach syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acquired cardiac septal defect
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acquired left ventricle outflow tract obstruction

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute aortic syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute cardiac event
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute coronary syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute left ventricular failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute myocardial infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute pulmonary oedema
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Acute right ventricular failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Adams-Stokes syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Administration site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Adrenal thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Adventitial cystic disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Agonal rhythm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Air embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Alveolar capillary dysplasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Amaurosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Amaurosis fugax
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Anaesthetic complication cardiac
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Anaphylactoid syndrome of pregnancy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aneurysm arteriovenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aneurysm perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aneurysm recanalisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aneurysm ruptured

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angina pectoris
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angina unstable
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Anginal equivalent
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angiodysplasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angiogram abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angiogram cerebral abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angiogram peripheral abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Angiosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Anomalous atrioventricular excitation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Anterior spinal artery syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Antiphospholipid syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic aneurysm rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic aneurysm syphilitic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic bypass
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic dissection rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic elongation

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic embolus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic intramural haematoma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic surgery
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve disease mixed
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve incompetence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve prolapse
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve sclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic valve thickening
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortic wall hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aorto-atrial fistula
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aortogram abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Application site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arrhythmia

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arrhythmia neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arrhythmia supraventricular
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterectomy with graft replacement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial bypass operation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial dolichoectasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial fibrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial graft
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial intramural haematoma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial occlusive disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial revascularisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial spasm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial stiffness
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial therapeutic procedure

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterial wall hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arterioenteric fistula
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriogram abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriogram carotid abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriosclerosis Moenckeberg-type
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriosclerosis coronary artery
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriospasm coronary
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriotomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous fistula
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous fistula aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous fistula occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous fistula thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous graft aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous graft site necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous graft site stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteriovenous graft thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteritis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Arteritis coronary
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Artificial blood vessel occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Aseptic cavernous sinus thrombosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atherectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atheroembolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atherosclerotic plaque rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Athletic heart syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial appendage closure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial appendage resection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial conduction time prolongation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial enlargement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial fibrillation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial flutter
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial parasystole
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial septal defect acquired
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrial thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular block
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular block complete
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular block first degree
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular block second degree
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular conduction time shortened
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular dissociation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Atrioventricular node dysfunction

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Autoimmune myocarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Autoimmune pericarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Axillary vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	BRASH syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Basal ganglia infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Basal ganglia stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Baseline foetal heart rate variability disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Basilar artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Basilar artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Basilar artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Basilar artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Behcet's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Benedikt's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bezold-Jarisch reflex
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bifascicular block
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Biliary ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bleeding varicose vein
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Blindness transient
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Blood pressure fluctuation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Blood pressure inadequately controlled
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bloody discharge
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Blue toe syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bone infarction

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachial artery entrapment syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachiocephalic arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachiocephalic artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachiocephalic artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachiocephalic vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachiocephalic vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brachiocephalic vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bradyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bradycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bradycardia foetal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bradycardia neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brain hypoxia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brain stem embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brain stem infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brain stem ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brain stem stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brain stem thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bronchial artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Brugada syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Budd-Chiari syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bundle branch block
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bundle branch block bilateral
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bundle branch block left

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Bundle branch block right
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	CT hypotension complex
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Calcium embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Capillary disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Capillary fragility
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Capillary leak syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Capsular warning syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carcinoid heart disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac amyloidosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac arrest
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac arrest neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac asthma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac autonomic neuropathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac complication associated with device
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac contusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac discomfort
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac failure acute
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac failure chronic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac failure congestive

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac failure high output
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac fibrillation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac flutter
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac function disturbance postoperative
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac granuloma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac herniation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac iron overload
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac perfusion defect
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac polyp
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac procedure complication
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac pseudoaneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac sarcoidosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac septal hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac steatosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac tamponade
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac valve discolouration
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac valve sclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac valve thickening
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac vein dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac vein perforation

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac ventricular disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac ventricular scarring
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiac ventricular thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardio-respiratory arrest
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardio-respiratory arrest neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardio-respiratory distress
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiogenic shock
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiohepatic syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiomegaly
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiomyopathy acute
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiomyopathy alcoholic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiomyopathy neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiopulmonary failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiorenal syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiotoxicity
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiovascular deconditioning
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiovascular disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiovascular insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiovascular somatic symptom disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cardiovascular symptom
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid aneurysm rupture

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid arterial embolus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery bypass
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery dolichoectasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotid endarterectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Carotidynia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Catecholamine crisis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Catheter directed thrombolysis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Catheter site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Catheterisation venous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cavernous sinus thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cement embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Central bradycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Central nervous system necrosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Central venous catheterisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar atherosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebellar stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral aneurysm perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral aneurysm ruptured syphilitic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral artery restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral artery stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral circulatory failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral congestion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral gas embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral hypoperfusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral infarction foetal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral microembolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral microinfarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral septic infarct
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral small vessel ischaemic disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral vascular occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral vasoconstriction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral venous sinus thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebral venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrospinal thrombotic tamponade
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrovascular accident
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrovascular accident prophylaxis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrovascular disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrovascular insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrovascular operation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cerebrovascular stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Charcot-Bouchard microaneurysms
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Chondronecrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Chordae tendinae rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Choroidal infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Chronic coronary syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Chronic left ventricular failure

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Chronic right ventricular failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Chronotropic incompetence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Circulatory collapse
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Circulatory failure neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Claude's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Claudication of jaw muscles
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coeliac artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coeliac artery compression syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coeliac artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coeliac artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Colitis ischaemic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Collateral circulation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Colon gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Complications of transplanted heart
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Compression garment application
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Conduction disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Congenital coronary artery malformation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Congenital pulmonary hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Congenital rubella syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Congestive cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cor pulmonale
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cor pulmonale acute
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cor pulmonale chronic

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary arterial stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery bypass
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery compression
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery reocclusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery surgery
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary bypass stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary bypass thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary endarterectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary no-reflow phenomenon
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary ostial stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary revascularisation

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary sinus dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary sinus injury
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary steal syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary vascular graft occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary vascular graft stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Coronary vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cryoglobulinaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Cyanosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Deep vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Deep vein thrombosis postoperative
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Defect conduction intraventricular
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Degenerative aortic valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Degenerative mitral valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Degenerative multivalvular disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Degenerative tricuspid valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Delayed ischaemic neurological deficit
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dependent rubor
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Device embolisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Device occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Device related thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diabetic arteritis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diabetic cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diabetic coronary microangiopathy

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diabetic macroangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diabetic microangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diabetic vascular disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dialysis hypotension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dialysis induced hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diaphragmatic hernia gangrenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diastolic dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diastolic hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diastolic hypotension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diffuse vasculitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dilatation atrial
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dilatation of sinotubular junction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dilatation ventricular
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Diplegia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Directional Doppler flow tests abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Disseminated intravascular coagulation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Disseminated intravascular coagulation in newborn
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Distributive shock
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dressler's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Dry gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Elephantiasis nostras verrucosa
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolia cutis medicamentosa
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolic cerebellar infarction

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolic cerebral infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolic pneumonia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolic stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolism arterial
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Embolism venous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endarterectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocardial disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocardial fibrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocardial varices
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocarditis fibroplastica
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocarditis noninfective
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocarditis rheumatic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endocrine hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Endothelial dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Eosinophilic myocarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Erythrocyanosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Erythromelalgia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Essential hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Eustachian valve hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Exsanguination
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Extrasystoles
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Extravasation blood

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Extremity necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Extrinsic iliac vein compression
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Eye infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	False lumen dilatation of aortic dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Fat embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Fat embolism syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral artery perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral hernia gangrenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral hernia strangulated
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Femoral vein perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Fibromuscular dysplasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Fluorescence angiogram abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Flushing
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal cardiac arrest
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal cardiac disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal cerebrovascular disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal heart rate acceleration abnormality
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal heart rate deceleration abnormality
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal heart rate disorder

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal placental thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foetal tachyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foix-Chavany-Marie syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foreign body embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Foville syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Frederick's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastric infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastric ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastrocardiac syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastrointestinal gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastrointestinal ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastrointestinal mucosal necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastrointestinal necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Gastrointestinal stoma necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Giant cell arteritis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Giant cell myocarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Graft ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Graft thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Granulomatosis with polyangiitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Grey syndrome neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haematocoele
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haematoma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemodynamic instability

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemodynamic rebound
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhage coronary artery
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhage neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhagic adrenal infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhagic cerebral infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhagic infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhagic stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhagic transformation stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhagic vasculitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Haemorrhoids thrombosed
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart alternation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart disease congenital
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart injury
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart transplant rejection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart valve calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart valve incompetence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart valve stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heart-lung transplant rejection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hemiparesis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hemiplegia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heparin-induced thrombocytopenia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic artery aneurysm

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic vascular thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic vein embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatic vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hepatojugular reflux
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Heritable pulmonary arterial hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hernia gangrenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hiatus hernia strangulated
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hoigne's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Holiday heart syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Homans' sign positive
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hot flush
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hyperaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hyperdynamic left ventricle
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hyperkinetic heart syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypersensitivity myocarditis

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertension neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive angiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive cardiomegaly
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive cerebrovascular disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive crisis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive emergency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive encephalopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive end-organ damage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive heart disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive nephropathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypertensive urgency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypoperfusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypotension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypotensive crisis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypothenar hammer syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypovolaemic shock
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Hypoxic-ischaemic encephalopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ileal gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery embolism

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac vein perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Iliac vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Immune-mediated myocarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Implant site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Incision site vessel occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Incisional hernia gangrenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Infective aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Infective thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inferior vena cava dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inferior vena cava perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inferior vena cava stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inferior vena cava syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inferior vena caval occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Infusion site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inguinal hernia gangrenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inguinal hernia strangulated

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Injection site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Inner ear infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Instillation site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intermittent claudication
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Internal capsule infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Internal carotid artery deformity
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Internal haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Interventricular septum rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intestinal angina
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intestinal gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intestinal infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intestinal ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intestinal strangulation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intra-aortic balloon placement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intracardiac mass
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intracardiac thrombus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intracranial aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intracranial artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intraoperative cerebral artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intrapericardial thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intratumoural aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Intravascular gas
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemia

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic cerebral infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic cholecystitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic enteritis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic gastritis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic hepatitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic limb pain
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic mitral regurgitation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic nephropathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic pancreatitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ischaemic stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Jejunal gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Jugular vein distension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Jugular vein embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Jugular vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Jugular vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Junctional ectopic tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Kawasaki's disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Kounis syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Kyphoscoliotic heart disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Labile blood pressure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Labile hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lacunar infarction

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lacunar stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lambl's excrescences
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Larsen syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lateral medullary syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left atrial appendage closure implant
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left atrial dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left atrial enlargement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left atrial hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular diastolic collapse
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular enlargement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular heave
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Left ventricular hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lemierre syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lenegre's disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Leriche syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Loeys-Dietz syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Long QT syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Low cardiac output syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lower limb artery perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lupus endocarditis

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3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lupus myocarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lupus vasculitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphangiectasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphatic fistula
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphocele
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphoedema
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphorrhoea
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Lymphostasis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	MAGIC syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Macroangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mahler sign
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Malignant atrophic papulosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Malignant hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Malignant hypertensive heart disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Malnutrition-inflammation-atherosclerosis syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Man-in-the-barrel syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Maternal hypertension affecting foetus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	May-Thurner syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Medical device site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric arterial occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric artery aneurysm

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric artery stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric phlebosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric vascular insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric vascular occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mesenteric venous occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Metabolic cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Metastatic pulmonary embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Microangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Microembolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Microscopic polyangiitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Microvascular coronary artery disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Migrainous infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Millard-Gubler syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve disease mixed
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve incompetence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve prolapse

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve sclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Mitral valve thickening
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Monoparesis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Monoplegia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Moyamoya disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial depression
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial fibrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial hypoperfusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial hypoxia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial oedema
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial reperfusion injury
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocardial stunning
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myocarditis post infection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Myxomatous mitral valve degeneration
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Necrosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Necrosis ischaemic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Necrosis of artery
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Negative cardiac inotropic effect
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal bradyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal cardiac failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal hypotension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal sinus bradycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal sinus tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal tachyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neonatal tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neovascularisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neurogenic hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Neurogenic shock
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Newborn persistent pulmonary hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Nitritoid reaction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Nodal arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Nodal rhythm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Non-dipping
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Non-obstructive cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Nonreassuring foetal heart rate pattern
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Obesity cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Obstetrical pulmonary embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Obstructive shock

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Oculocardiac reflex
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Oedema due to cardiac disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Omental infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Omental necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ophthalmic artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ophthalmic vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Optic nerve infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Orthostatic hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Orthostatic hypotension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Orthostatic intolerance
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ovarian vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paget-Schroetter syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pallor
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Palpitations
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pancreatic infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Papillary muscle disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Papillary muscle haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Papillary muscle infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Papillary muscle rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Papillophlebitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paradoxical embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paradoxical pressor response
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paraneoplastic erythromelalgia

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paraneoplastic thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paraparesis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paraplegia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Parasystole
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paresis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paroxysmal arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paroxysmal atrioventricular block
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Paroxysmal nocturnal haemoglobinuria
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pelvic venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Penetrating aortic ulcer
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Penetrating atherosclerotic ulcer
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Penile artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Penile vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Percutaneous coronary intervention
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Perforation of great vessels
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial cyst
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial effusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial fibrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial mass
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericardial rub

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericarditis adhesive
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericarditis constrictive
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericarditis lupus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericarditis rheumatic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pericarditis uraemic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral arterial occlusive disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral arterial reocclusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery aneurysm rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery bypass
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery haematoma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery surgery
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral circulatory failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral coldness
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral endarterectomy

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral revascularisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral vascular disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral vein thrombus extension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peripheral venous disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Periphlebitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Peritoneal necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Phlebectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Phlebitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Phlebitis deep
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Phlebitis superficial
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Phlebolith
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Phlebosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pituitary infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Placental infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Plaque shift
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Plethoric face
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pleuropericarditis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pneumatic compression therapy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pneumopericardium
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Polyarteritis nodosa

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Poor peripheral circulation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Poor venous access
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Popliteal artery entrapment syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal pyaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal shunt procedure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal vein cavernous transformation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal vein embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portal vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portopulmonary hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Portosplenomesenteric venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Positive cardiac inotropic effect
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Positive vessel remodelling
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post angioplasty restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post procedural myocardial infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post procedural pulmonary embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post procedural stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post thrombotic retinopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post thrombotic syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Post-anoxic myoclonus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Postinfarction angina
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Postoperative thrombosis

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Postpartum thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Postpartum venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Postural orthostatic tachycardia syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Precerebral arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Precerebral artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Precerebral artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Precerebral artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Prehypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Prinzmetal angina
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Profundaplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Prosthetic cardiac valve thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Prosthetic vessel implantation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pseudovasculitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary arterial hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary artery therapeutic procedure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary artery wall hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary congestion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary endarterectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary hypertension

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary hypertensive crisis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary microemboli
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary oedema
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary oedema neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary oil microembolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary tumour thrombotic microangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary valve calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary valve incompetence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary valve sclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary valve stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary valve thickening
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary veno-occlusive disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary venous hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulmonary venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Pulseless electrical activity
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Quadriparesis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Quadriplegia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Raymond-Cestan syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Raynaud's phenomenon

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Rebound tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery fibromuscular dysplasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal cortical necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal infarct
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal transplant torsion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal vascular thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal vein embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renal-limited thrombotic microangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Renovascular hypertension

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Reperfusion arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Reperfusion injury
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Restrictive cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal aneurysm rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal vascular thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinal vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retinopathy hypertensive
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Retrograde portal vein flow
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Revascularisation procedure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Reversible cerebral vasoconstriction syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Reversible ischaemic neurological deficit
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Rheumatic heart disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Rheumatoid vasculitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Rhythm idioventricular
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right atrial dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right atrial enlargement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right atrial hypertrophy

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular diastolic collapse
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular enlargement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular heave
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right ventricular hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Right-to-left cardiac shunt
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ruptured cerebral aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	SI QIII TIII pattern
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Secondary hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Seizure anoxic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Septic embolus
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Septic necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Septic pulmonary embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shock
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shock haemorrhagic
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shock symptom
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shoshin beriberi
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shunt aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shunt occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Shunt thrombosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sigmoid-shaped ventricular septum
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Silent myocardial infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinoatrial block
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinus arrest
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinus arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinus bradycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinus node dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinus tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Sinusoidal foetal heart rate pattern
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Small intestine gangrene
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Soft tissue necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spider vein
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spinal artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spinal artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spinal claudication
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spinal cord infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spinal cord ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spinal stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splanchnic hypoperfusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spleen ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic artery thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic embolism

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic vein aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Splenic vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spontaneous amputation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Spontaneous heparin-induced thrombocytopenia syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Steal syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Stoma site ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Stoma site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Strangulated hernia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Strangulated incisional hernia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Strangulated umbilical hernia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Stress cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Stroke in evolution
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Strokectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian artery thrombosis

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian coronary steal syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian steal syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian vein occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian vein perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian vein stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subclavian vein thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subendocardial haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subendocardial ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subgaleal haematoma
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subgaleal haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Subvalvular aortic stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superficial vein prominence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superior sagittal sinus thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superior vena cava dilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superior vena cava occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superior vena cava perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superior vena cava stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Superior vena cava syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supine hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supra-aortic trunk sclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supra-aortic trunk stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supravalvular aortic stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supraventricular extrasystoles

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supraventricular tachyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Supraventricular tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Surgical vascular shunt
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Susac's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Systolic anterior motion of mitral valve
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Systolic dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Systolic hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tachyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tachycardia foetal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tachycardia induced cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tachycardia paroxysmal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Takayasu's arteritis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Testicular infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thalamic infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thromboangiitis obliterans
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thromboembolectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombolysis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombophlebitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombophlebitis migrans
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombophlebitis neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombophlebitis septic

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombophlebitis superficial
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombosed varicose vein
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombosis corpora cavernosa
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombosis in device
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombosis mesenteric vessel
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombosis prophylaxis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombotic cerebral infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombotic microangiopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombotic stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thrombotic thrombocytopenic purpura
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thyroid infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Thyrotoxic cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tongue infarction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tongue necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Torsade de pointes
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Toxic cardiomyopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Transient ischaemic attack
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Transverse sinus thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve incompetence
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve prolapse

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve sclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tricuspid valve thickening
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Trifascicular block
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Truncus coeliacus thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tumour embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tumour necrosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tumour thrombectomy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tumour thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Tyramine reaction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ultrasonic angiogram abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ultrasound Doppler abnormal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Umbilical cord occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Umbilical cord thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Umbilical hernia gangrenous
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vaccination site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Varicophlebitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Varicose ulceration
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Varicose vein
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Varicose vein ruptured
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular access site dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular access site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular access steal syndrome

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular anastomosis aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular calcification
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular cognitive impairment
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular compression
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular dementia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular device occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular encephalopathy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular fragility
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular graft
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular graft occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular graft restenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular graft stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular graft thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular hyalinosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular operation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular pain
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular pseudoaneurysm thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular shunt
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular stenosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular stent occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular stent stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular stent thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular wall discolouration
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vascular wall hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vasculitis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vasculitis necrotising
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vasoconstriction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vasodilatation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vasodilation procedure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vasospasm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vein collapse
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vein discolouration
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vein disorder
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vein dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vein rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vein wall hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vena cava embolism
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vena cava filter insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vena cava filter removal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vena cava thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venogram abnormal

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venoocclusive disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venoocclusive liver disease
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous angioplasty
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous haemorrhage
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous intravasation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous operation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous recanalisation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous repair
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous stent insertion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous thrombosis in pregnancy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous thrombosis limb
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous thrombosis neonatal
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Venous valve ruptured
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricle rupture
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular asystole
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular compliance decreased

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User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular dysfunction
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular dyskinesia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular dyssynchrony
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular enlargement
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular extrasystoles
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular failure
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular fibrillation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular flutter
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular hyperkinesia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular hypertrophy
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular hypokinesia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular parasystole
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular pre-excitation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular remodelling
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular septal defect acquired
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular tachyarrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Ventricular tachycardia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebral artery aneurysm
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebral artery arteriosclerosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebral artery dissection
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebral artery occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebral artery stenosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebral artery thrombosis

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebrobasilar dolichoectasia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebrobasilar insufficiency
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vertebrobasilar stroke
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vessel perforation
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vessel puncture site occlusion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vessel puncture site thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Vestibular ischaemia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Visceral congestion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Visceral venous thrombosis
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Visual acuity reduced transiently
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Visual midline shift syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Wandering pacemaker
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Weber's syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Wellens' syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	White coat hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	White matter lesion
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Withdrawal arrhythmia
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Withdrawal hypertension
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Wolff-Parkinson-White syndrome
3-point MACE	3-Point MACE Part 2/2 (BIcMQ)	NARROW	AESDTH eq 'Y' or AOUT eq 'Fatal'	Wyburn Mason's syndrome
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Cardiac arrest
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Cardiac death
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Cardiac fibrillation
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Cardio-respiratory arrest
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Electrocardiogram QT interval abnormal
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Electrocardiogram QT prolonged

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Listing 1.4.19 Listing of preferred terms that define User Defined Adverse Event Categories

User Defined Adverse Event Category	UDAEC Search Criteria	UDAEC Scope	Additional condition	Preferred Term
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Electrocardiogram U wave inversion
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Electrocardiogram U wave present
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Electrocardiogram U-wave abnormality
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Electrocardiogram repolarisation abnormality
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Long QT syndrome
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Long QT syndrome congenital
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Loss of consciousness
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Sudden cardiac death
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Sudden death
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Syncope
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Torsade de pointes
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Ventricular arrhythmia
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Ventricular fibrillation
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Ventricular flutter
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Ventricular tachyarrhythmia
Torsade de pointes	Torsade de pointes/QT prolongation (SMQ)	BROAD		Ventricular tachycardia

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1.1.5 Adverse events on SOC level

Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	640.8	35	1	2.9	0.6	154.1	0.3793	-8.3	(-31.5,6.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.24	(0.01,3.38)	0.26	(0.01,2.76) (0.02,2.65)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.3	1756.0	35	9	25.7	0.6	1543.3	0.9152	-2.1	(-30.0,22.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.90	(0.25,3.52)	0.93	(0.36,2.95) (0.36,2.36)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Infections and infestations

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	6	17.1	0.6	987.2	0.3794	11.6	(-11.8,29.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.52	(0.46,85.94)	3.09	(0.50,78.78) (0.40,23.71)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	619.1	35	4	11.4	0.6	664.1	1.0000	0.3	(-24.0,18.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.16,8.79)	1.03	(0.19,7.65) (0.21,5.09)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	624.4	35	3	8.6	0.6	484.8	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	624.4	35	4	11.4	0.6	627.0	1.0000	0.3	(-24.0,18.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.16,8.79)	1.03	(0.19,7.65) (0.21,5.09)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	961.2	35	4	11.4	0.6	655.2	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	9	50.0	0.2	3612.4	35	18	51.4	0.5	3844.7	0.9735	1.4	(-27.1,30.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.06	(0.33,3.39)	1.03	(0.60,2.12) (0.59,1.81)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	459.4	35	3	8.6	1.9	161.9	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Gastrointestinal disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	5	14.3	1.7	288.1	0.4577	8.7	(-14.4,25.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.83	(0.35,71.13)	2.57	(0.41,65.20) (0.32,20.39)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.3	1438.0	35	9	25.7	1.6	575.7	0.9152	-2.1	(-30.0,22.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.90	(0.25,3.52)	0.93	(0.36,2.95) (0.36,2.36)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Overall	18	1	5.6	0.5	190.2	35	9	25.7	1.5	587.0	0.1331	20.2 (-3.9,38.8)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	5.88	(0.83,137.18)	4.63	(0.83,122.06) (0.64,33.73)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	448.2	35	7	20.0	1.6	440.8	0.4666	8.9	(-16.5,28.6)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.00	(0.38,15.33)	1.80	(0.45,17.10) (0.42,7.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	450.9	35	3	8.6	1.7	174.5	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	676.4	35	6	17.1	1.7	362.8	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	689.2	35	5	14.3	1.7	288.1	0.8862	-2.4	(-28.5,17.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	9	50.0	0.3	2883.6	35	19	54.3	1.1	1770.3	0.8734	4.3	(-24.2,32.3)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.19	(0.37,3.80)	1.09	(0.64,2.12) (0.62,1.89)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Blood and lymphatic system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.6	319.0	35	3	8.6	4.6	64.8	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Gastrointestinal disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	6	17.1	4.3	139.1	0.3794	11.6	(-11.8,29.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	3.52	(0.46,85.94)	3.09	(0.50,78.78) (0.40,23.71)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	5	27.8	0.5	998.0	35	9	25.7	4.0	224.8	0.9152	-2.1	(-30.0,22.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.90	(0.25,3.52)	0.93	(0.36,2.95) (0.36,2.36)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	12	34.3	3.4	355.8	0.0264	28.7	(2.2,47.9)
Sex													
Male	3	1	33.3	0.1	1739.3	14	3	21.4	1.6	186.4	1.0000	-11.9	(-70.8,35.2)
Female	15	0	0.0	0.8	0.0	21	9	42.9	1.8	510.4	0.0035	42.9	(15.4,66.0)
Age													
>= 50 years	4	0	0.0	0.3	0.0	11	3	27.3	1.2	241.9	0.3537	27.3	(-33.5,61.0)
< 50 years	14	1	7.1	0.6	172.3	24	9	37.5	2.1	422.0	0.0631	30.4	(-1.3,53.9)
Race													
Asian	13	0	0.0	0.8	0.0	16	7	43.8	1.7	406.5	0.0096	43.8	(15.4,70.1)
White	5	1	20.0	0.1	1074.3	19	5	26.3	1.7	302.9	1.0000	6.3	(-46.1,40.8)
Region													
Europe + Africa + US	5	1	20.0	0.1	1074.3	21	6	28.6	1.8	333.1	1.0000	8.6	(-41.9,41.9)
Asia(ex Japan) + Japan	13	0	0.0	0.8	0.0	14	6	42.9	1.6	381.8	0.0082	42.9	(13.7,71.1)
BMI													
< 25 kg/m2	9	1	11.1	0.3	372.7	15	4	26.7	1.7	234.9	0.4530	15.6	(-25.7,47.3)
25 to < 30 kg/m2	6	0	0.0	0.5	0.0	10	4	40.0	0.8	487.0	0.1402	40.0	(-10.6,73.8)
>= 30 kg/m2	3	0	0.0	0.1	0.0	10	4	40.0	0.8	471.3	0.2779	40.0	(-31.3,75.5)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	8.87	(1.29,201.76)	6.17	(1.02,168.54) (0.87,43.78)	
Sex					NC
Male	0.55	(0.03,21.23)	0.64	(0.10,16.64) (0.10,4.25)	
Female	inf	(3.51, inf)	inf	(1.62, inf)	
Age					NC
>= 50 years	inf	(0.32, inf)	inf	(0.31, inf)	
< 50 years	7.80	(1.02,184.62)	5.25	(0.98,140.82) (0.74,37.20)	
Race					NC
Asian	inf	(2.92, inf)	inf	(1.34, inf)	
White	1.43	(0.13,42.05)	1.32	(0.24,33.81) (0.20,8.87)	
Region					NC
Europe + Africa + US	1.60	(0.16,45.83)	1.43	(0.30,37.00) (0.22,9.35)	
Asia(ex Japan) + Japan	inf	(2.70, inf)	inf	(1.33, inf)	
BMI					NC
< 25 kg/m2	2.91	(0.29,80.39)	2.40	(0.35,61.57) (0.32,18.26)	
25 to < 30 kg/m2	inf	(0.91, inf)	inf	(0.70, inf)	
>= 30 kg/m2	inf	(0.40, inf)	inf	(0.43, inf)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Mutation status IL36RN													
Yes	2	1	50.0			5	3	60.0					
No	12	0	0.0			24	5	20.8					
Mutation status IL36RN after DNA resequencing													
Yes	6	1	16.7	0.3	306.9	8	3	37.5	1.2	251.3	0.6414	20.8	(-32.5,65.7)
No	11	0	0.0	0.5	0.0	21	5	23.8	1.7	292.7	0.1279	23.8	(-5.7,47.2)
Baseline GPPGA pustulation subscore													
<4	12	0	0.0	0.4	0.0	22	9	40.9	2.0	448.5	0.0148	40.9	(8.9,63.6)
=4	6	1	16.7	0.4	234.1	13	3	23.1	1.4	219.6	0.9119	6.4	(-41.0,42.7)
Baseline GPPGA score													
=3	15	0	0.0	0.8	0.0	28	12	42.9	2.6	461.9	0.0051	42.9	(11.6,62.8)
=4	3	1	33.3	0.1	1826.3	7	0	0.0	0.8	0.0	0.2974	-33.3	(-90.6,22.4)
Baseline plaque psoriasis													
Yes	3	0	0.0			6	1	16.7					
No	15	1	6.7			29	11	37.9					
Background treatment prior to randomization													
Yes	8	1	12.5	0.2	401.4	15	5	33.3	0.8	589.1	0.3866	20.8	(-24.2,52.9)
No	10	0	0.0	0.6	0.0	20	7	35.0	2.5	277.3	0.0383	35.0	(2.0,59.2)

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo: Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Mutation status IL36RN				
Yes				
No				
Mutation status IL36RN after DNA resequencing				NC
Yes	3.00 (0.21,93.71)	2.25	(0.29,58.85) (0.30,16.63)	
No	inf (0.99, inf)	inf	(0.73, inf)	
Baseline GPPGA pustulation subscore				NC
<4	inf (2.58, inf)	inf	(1.10, inf)	
=4	1.50 (0.12,46.97)	1.38	(0.17,35.82) (0.18,10.71)	
Baseline GPPGA score				NC
=3	inf (3.73, inf)	inf	(1.62, inf)	
=4	0.00 (0.00,3.86)	0.00	(0.00,5.95)	
Baseline plaque psoriasis				
Yes				
No				
Background treatment prior to randomization				NC
Yes	3.50 (0.36,94.38)	2.67	(0.49,69.03) (0.37,19.09)	
No	inf (1.60, inf)	inf	(0.94, inf)	

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Speso 900 mg IV SD vs Placebo Risk diff. (95% CI)
Pain VAS score at baseline												
<= 40	2	0	0.0			1	0	0.0				
> 40	16	1	6.3			34	12	35.3				
Hepatic impairment at baseline												
Yes	0	0	na			0	0	na				
No	18	1	5.6			32	10	31.3				
Renal impairment at baseline												
Normal	16	1	6.3			26	8	30.8				
Mild	1	0	0.0			6	4	66.7				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Pain VAS score at baseline				
<= 40				
> 40				
Hepatic impairment at baseline				
Yes				
No				
Renal impairment at baseline				
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.6	313.5	35	7	20.0	3.7	186.8	0.4666	8.9	(-16.5,28.6)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.00	(0.38,15.33)	1.80	(0.45,17.10) (0.42,7.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Metabolism and nutrition disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.6	314.9	35	4	11.4	4.3	92.2	1.0000	0.3	(-24.0,18.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.16,8.79)	1.03	(0.19,7.65) (0.21,5.09)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.6	472.3	35	6	17.1	4.1	146.5	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Nervous system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.6	478.5	35	5	14.3	4.4	114.8	0.8862	-2.4	(-28.5,17.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)		p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)		

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	9	50.0	0.5	1933.7	35	21	60.0	2.6	819.5	0.7606	10.0	(-18.5,37.8)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.50	(0.46,4.83)	1.20	(0.72,2.43) (0.70,2.05)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.4 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	987.2	35	5	14.3	0.6	833.9	0.8862	-2.4	(-28.5,17.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.4 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.5 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	702.4	35	5	14.3	1.6	304.9	0.8862	-2.4	(-28.5,17.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.5 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.6 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.7	408.9	35	6	17.1	4.1	146.3	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.6 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Cardiac disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	297.0	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Cardiac disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	2	5.7	0.6	309.5	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	944.6	35	6	17.1	0.6	978.3	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	3	8.6	0.6	470.3	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	3	8.6	0.6	491.4	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	624.4	35	3	8.6	0.6	484.8	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	624.4	35	2	5.7	0.6	312.2	0.7606	-5.4	(-28.9,11.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.48	(0.05,5.09)	0.51	(0.04,7.59) (0.08,3.36)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	961.2	35	3	8.6	0.6	478.5	0.4577	-8.1	(-33.4,10.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)		p-value**
Overall	0.47	(0.07,3.06)	0.51	(0.09,2.95) (0.12,2.30)		

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Renal and urinary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	2	5.7	0.6	314.9	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Renal and urinary disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	4	22.2	0.3	1292.9	35	7	20.0	0.6	1162.2	0.8928	-2.2	(-28.9,20.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.88	(0.22,3.94)	0.90	(0.30,4.09) (0.30,2.67)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Vascular disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	2	5.7	1.9	106.3	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Cardiac disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	192.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Cardiac disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Gastrointestinal disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	3	8.6	1.8	163.8	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	680.6	35	6	17.1	1.7	350.1	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	3	8.6	1.9	161.4	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	3	8.6	1.8	164.0	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	450.9	35	2	5.7	1.8	111.9	0.7606	-5.4	(-28.9,11.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.48	(0.05,5.09)	0.51	(0.04,7.59) (0.08,3.36)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.5	388.6	35	3	8.6	1.8	165.3	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	689.2	35	4	11.4	1.8	220.7	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Renal and urinary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.8	111.4	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Renal and urinary disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Respiratory, thoracic and mediastinal disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	4	22.2	0.4	924.7	35	7	20.0	1.7	422.6	0.8928	-2.2	(-28.9,20.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.88	(0.22,3.94)	0.90	(0.30,4.09) (0.30,2.67)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Vascular disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	155.4	35	2	5.7	4.7	43.0	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Cardiac disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Cardiac disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	3	8.6	4.6	65.1	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.8	236.4	35	5	14.3	4.6	109.8	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	5	14.3	4.6	108.1	0.4577	8.7	(-14.4,25.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.83	(0.35,71.13)	2.57	(0.41,65.20) (0.32,20.39)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Injury, poisoning and procedural complications

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.9	40.8	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Injury, poisoning and procedural complications

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	155.4	35	3	8.6	4.6	65.3	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.6	314.9	35	3	8.6	4.6	65.9	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Metabolism and nutrition disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.9	232.6	35	3	8.6	4.6	65.5	0.8734	-2.5	(-26.5,15.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.75	(0.10,6.88)	0.77	(0.13,7.64) (0.14,4.21)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.6	478.5	35	4	11.4	4.6	87.4	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Nervous system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Renal and urinary disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.6	43.8	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Renal and urinary disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Respiratory, thoracic and mediastinal disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Respiratory, thoracic and mediastinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.8	358.1	35	7	20.0	4.3	161.5	0.8815	3.3	(-22.7,24.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.25	(0.28,6.69)	1.20	(0.35,7.59) (0.35,4.09)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Vascular disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Vascular disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	299.4	35	3	8.6	0.6	474.4	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)		p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)		

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	1	2.9	0.6	154.1	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Hepatobiliary disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Infections and infestations

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	3	8.6	0.6	476.4	0.3121	8.6	(-11.7,23.1)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.45, inf)	inf	(0.36, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	294.6	35	1	2.9	0.7	153.5	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Psychiatric disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	294.6	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Psychiatric disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	952.8	35	6	17.1	0.6	1014.6	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	195.3	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.8	108.4	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	193.3	35	3	8.6	1.8	167.3	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Hepatobiliary disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	1	2.9	1.9	53.5	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Hepatobiliary disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	6	17.1	1.6	371.4	0.0829	17.1	(-3.8,33.6)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(1.20, inf)	inf	(0.79, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	191.2	35	4	11.4	1.8	223.1	0.7740	5.9	(-17.0,22.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)		p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)		

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	212.4	35	2	5.7	1.8	108.5	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Psychiatric disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	191.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Psychiatric disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.5	602.1	35	7	20.0	1.6	431.2	0.8815	3.3	(-22.7,24.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.25	(0.28,6.69)	1.20	(0.35,7.59) (0.35,4.09)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Blood and lymphatic system disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	116.7	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Blood and lymphatic system disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Gastrointestinal disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	3	8.6	4.7	63.6	0.3121	8.6	(-11.7,23.1)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Gastrointestinal disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.45, inf)	inf	(0.36, inf)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.7	269.6	35	4	11.4	4.7	85.7	1.0000	0.3	(-24.0,18.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.16,8.79)	1.03	(0.19,7.65) (0.21,5.09)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Hepatobiliary disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	1	2.9	4.8	20.9	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Hepatobiliary disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	7	20.0	3.8	186.1	0.0480	20.0	(-1.4,36.9)
Sex													
Male	3	0	0.0	0.1	0.0	14	1	7.1	1.8	56.7	1.0000	7.1	(-59.3,35.9)
Female	15	0	0.0	0.8	0.0	21	6	28.6	2.0	300.2	0.0296	28.6	(5.0,52.4)
Age													
>= 50 years	4	0	0.0	0.3	0.0	11	2	18.2	1.2	161.3	0.5651	18.2	(-42.2,51.8)
< 50 years	14	0	0.0	0.6	0.0	24	5	20.8	2.5	198.3	0.0997	20.8	(-3.3,42.2)
Race													
Asian	13	0	0.0	0.8	0.0	16	4	25.0	1.8	218.7	0.0742	25.0	(-3.1,52.4)
White	5	0	0.0	0.1	0.0	19	3	15.8	1.9	155.2	0.5151	15.8	(-35.6,41.1)
Region													
Europe + Africa + US	5	0	0.0	0.1	0.0	21	3	14.3	2.2	137.3	0.5697	14.3	(-37.0,37.3)
Asia(ex Japan) + Japan	13	0	0.0	0.8	0.0	14	4	28.6	1.6	253.6	0.0534	28.6	(-0.5,58.1)
BMI													
< 25 kg/m2	9	0	0.0	0.3	0.0	15	2	13.3	1.9	107.7	0.3709	13.3	(-20.0,41.0)
25 to < 30 kg/m2	6	0	0.0	0.5	0.0	10	2	20.0	0.8	241.9	0.3585	20.0	(-26.4,55.8)
>= 30 kg/m2	3	0	0.0	0.1	0.0	10	3	30.0	1.1	278.1	0.4344	30.0	(-41.0,67.7)
Mutation status IL36RN													
Yes	2	0	0.0			5	2	40.0					
No	12	0	0.0			24	3	12.5					
Mutation status IL36RN after DNA resequencing													

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(1.48, inf)	inf	(0.91, inf)	
Sex					NC
Male	inf	(0.02, inf)	inf	(0.02, inf)	
Female	inf	(1.82, inf)	inf	(1.06, inf)	
Age					NC
>= 50 years	inf	(0.16, inf)	inf	(0.14, inf)	
< 50 years	inf	(1.10, inf)	inf	(0.80, inf)	
Race					NC
Asian	inf	(1.17, inf)	inf	(0.84, inf)	
White	inf	(0.22, inf)	inf	(0.20, inf)	
Region					NC
Europe + Africa + US	inf	(0.20, inf)	inf	(0.18, inf)	
Asia(ex Japan) + Japan	inf	(1.37, inf)	inf	(0.99, inf)	
BMI					NC
< 25 kg/m2	inf	(0.28, inf)	inf	(0.24, inf)	
25 to < 30 kg/m2	inf	(0.28, inf)	inf	(0.22, inf)	
>= 30 kg/m2	inf	(0.25, inf)	inf	(0.26, inf)	
Mutation status IL36RN					
Yes					
No					
Mutation status IL36RN after DNA resequencing					NC

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Yes	6	0	0.0	0.3	0.0	8	2	25.0	1.4	140.5	0.2711	25.0	(-23.6,66.1)
No	11	0	0.0	0.5	0.0	21	3	14.3	1.8	165.3	0.3134	14.3	(-15.1,36.3)
Baseline GPPGA pustulation subscore													
<4	12	0	0.0	0.4	0.0	22	5	22.7	2.4	209.2	0.0885	22.7	(-6.1,45.4)
=4	6	0	0.0	0.4	0.0	13	2	15.4	1.4	145.8	0.4600	15.4	(-30.9,45.9)
Baseline GPPGA score													
=3	15	0	0.0	0.8	0.0	28	7	25.0	3.0	234.3	0.0505	25.0	(0.0,44.9)
=4	3	0	0.0			7	0	0.0					
Baseline plaque psoriasis													
Yes	3	0	0.0			6	1	16.7					
No	15	0	0.0			29	6	20.7					
Background treatment prior to randomization													
Yes	8	0	0.0	0.3	0.0	15	3	20.0	1.2	254.2	0.3175	20.0	(-17.6,48.1)
No	10	0	0.0	0.6	0.0	20	4	20.0	2.6	154.9	0.1609	20.0	(-12.3,44.1)
Pain VAS score at baseline													
<= 40	2	0	0.0			1	0	0.0					
> 40	16	0	0.0			34	7	20.6					
Hepatic impairment at baseline													
Yes	0	0	na			0	0	na					
No	18	0	0.0			32	5	15.6					
Renal impairment at baseline													

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Yes	inf	(0.36, inf)	inf	(0.28, inf)	
No	inf	(0.46, inf)	inf	(0.38, inf)	
Baseline GPPGA pustulation subscore					NC
<4	inf	(1.03, inf)	inf	(0.73, inf)	
=4	inf	(0.21, inf)	inf	(0.19, inf)	
Baseline GPPGA score					NC
=3	inf	(1.60, inf)	inf	(0.94, inf)	
=4					
Baseline plaque psoriasis					
Yes					
No					
Background treatment prior to randomization					NC
Yes	inf	(0.48, inf)	inf	(0.42, inf)	
No	inf	(0.68, inf)	inf	(0.52, inf)	
Pain VAS score at baseline					
<= 40					
> 40					
Hepatic impairment at baseline					
Yes					
No					
Renal impairment at baseline					

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Normal	16	0	0.0			26	5	19.2				
Mild	1	0	0.0			6	2	33.3				
Moderate	0	0	na			1	0	0.0				
Severe	0	0	na			0	0	na				
ESRD	0	0	na			0	0	na				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Infections and infestations

Subgroup Category	Speso 900 mg IV SD vs Placebo			
	Odds ratio (95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Normal				
Mild				
Moderate				
Severe				
ESRD				

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Injury, poisoning and procedural complications

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	131.4	35	1	2.9	4.8	20.7	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Injury, poisoning and procedural complications

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Investigations

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.2	35	4	11.4	4.3	93.9	0.7740	5.9	(-17.0,22.7)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Investigations

Subgroup Category	Speso 900 mg IV SD vs Placebo					
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)		p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)		

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	150.9	35	2	5.7	4.7	42.2	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Musculoskeletal and connective tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Psychiatric disorders

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.2	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Psychiatric disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	4	22.2	0.8	525.5	35	8	22.9	4.0	197.7	1.0000	0.6	(-26.5,23.4)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.04	(0.26,4.56)	1.03	(0.35,5.62) (0.36,2.96)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	635.2	35	5	14.3	0.6	830.1	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	456.6	35	5	14.3	1.7	293.6	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Placebo N	Placebo n	Placebo %	Placebo Time at risk [pt-yrs]	Placebo Rate/100 pt-yrs	Speso 900 mg IV SD N	Speso 900 mg IV SD n	Speso 900 mg IV SD %	Speso 900 mg IV SD Time at risk [pt-yrs]	Speso 900 mg IV SD Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	131.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: General disorders and administration site conditions

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.7	268.6	35	5	14.3	4.3	115.6	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.5.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)
System Organ Class: Skin and subcutaneous tissue disorders

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.5.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 1 - SAF (OC)

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Table 1.5.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 4 - SAF (OC)

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Table 1.5.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity with >=5% occurrence in at least one treatment arm on SOC level overall and by subgroup up to week 12- SAF (OC)

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1.1.6 Adverse events on PT level

Table 1.6.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Overall	18	4	22.2	0.3	1404.8	35	2	5.7	0.6	313.5	0.1331	-16.5 (-41.6,3.8)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.21	(0.03,1.38)	0.26	(0.04,1.38) (0.05,1.27)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	0.3	619.1	35	0	0.0	0.7	0.0	0.0829	-11.1 (-34.7,1.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,1.08)	0.00	(0.00,1.35)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	7	38.9	0.3	2719.9	35	13	37.1	0.5	2499.1	0.9480	-1.7	(-30.7,25.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.1 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.93	(0.28,3.14)	0.96	(0.46,2.21) (0.46,1.97)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	4	22.2	0.4	980.5	35	2	5.7	1.9	107.6	0.1331	-16.5 (-41.6,3.8)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.21	(0.03,1.38)	0.26	(0.04,1.38) (0.05,1.27)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.5	382.5	35	1	2.9	1.9	51.5	0.3793	-8.3	(-31.5,6.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.24	(0.01,3.38)	0.26	(0.01,2.76) (0.02,2.65)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	0.5	394.9	35	0	0.0	1.9	0.0	0.0829	-11.1 (-34.7,1.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,1.08)	0.00	(0.00,1.35)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	218.7	35	4	11.4	1.8	220.7	0.7740	5.9	(-17.0,22.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	7	38.9	0.4	1839.4	35	15	42.9	1.3	1196.2	0.8850	4.0	(-25.0,30.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.2 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.18	(0.36,3.93)	1.10	(0.57,2.76) (0.55,2.21)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Overall	18	4	22.2	0.7	559.8	35	2	5.7	4.9	40.7	0.1331	-16.5 (-41.6,3.8)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.21	(0.03,1.38)	0.26	(0.04,1.38) (0.05,1.27)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.7	279.9	35	1	2.9	4.9	20.6	0.3793	-8.3	(-31.5,6.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.24	(0.01,3.38)	0.26	(0.01,2.76) (0.02,2.65)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	0.9	234.9	35	0	0.0	5.0	0.0	0.0829	-11.1 (-34.7,1.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,1.08)	0.00	(0.00,1.35)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.1	35	4	11.4	4.6	87.4	0.7740	5.9	(-17.0,22.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	7	38.9	0.7	1018.6	35	17	48.6	3.1	551.9	0.7740	9.7	(-19.5,36.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.3 Proportion and incidence rate of patients with adverse events with >=10% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.48	(0.46,4.92)	1.25	(0.65,3.12) (0.64,2.45)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.4 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	987.2	35	4	11.4	0.6	655.2	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.4 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.5 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.4	702.4	35	4	11.4	1.7	233.8	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.5 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.6 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Drug reaction with eosinophilia and systemic symptoms

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.8	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.6 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Drug reaction with eosinophilia and systemic symptoms

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.6 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.7	408.9	35	4	11.4	4.3	92.5	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.6 Proportion and incidence rate of patients with serious adverse events with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12- SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Erythropenia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Erythropenia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Cardiac disorders
Preferred term: Palpitations

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	297.0	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Cardiac disorders
Preferred term: Palpitations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Nausea

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	2	5.7	0.6	308.2	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Nausea

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Vomiting

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	1	2.9	0.7	153.5	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Vomiting

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Asthenia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	289.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Asthenia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.3	0.0	35	2	5.7	0.7	306.9	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	3	16.7	0.3	996.1	35	2	5.7	0.6	313.5	0.3121	-11.0 (-36.0,7.8)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.30	(0.03,2.29)	0.34	(0.04,2.00) (0.06,1.87)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Infections and infestations
Preferred term: Streptococcal infection

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Infections and infestations
Preferred term: Streptococcal infection

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil count increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil count increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil percentage increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil percentage increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Haematocrit decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Haematocrit decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Haemoglobin decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Haemoglobin decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Protein total decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Protein total decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Decreased appetite

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Decreased appetite

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Hyperuricaemia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	297.0	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Hyperuricaemia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Myalgia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Myalgia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Pain in extremity

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	299.4	35	2	5.7	0.6	309.5	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Pain in extremity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo	
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	0.3	619.1	35	0	0.0	0.7	0.0	0.0829	-11.1 (-34.7,1.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,1.08)	0.00	(0.00,1.35)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	299.4	35	3	8.6	0.6	478.5	0.8564	3.0	(-19.5,19.0)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.59	(0.16,44.29)	1.54	(0.17,39.66) (0.17,13.79)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Anxiety

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	297.0	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Anxiety

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Respiratory, thoracic and mediastinal disorders
Preferred term: Cough

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Respiratory, thoracic and mediastinal disorders
Preferred term: Cough

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Dermatitis allergic

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	289.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Dermatitis allergic

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.3	969.7	35	4	11.4	0.6	635.2	0.7741	-5.2	(-30.7,14.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.65	(0.12,3.88)	0.69	(0.16,4.57) (0.17,2.74)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Vascular disorders
Preferred term: Hypotension

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	301.9	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.7 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Vascular disorders
Preferred term: Hypotension

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Erythropenia

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Erythropenia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Cardiac disorders
Preferred term: Palpitations

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	192.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Cardiac disorders
Preferred term: Palpitations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Nausea

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	3	8.6	1.8	163.5	0.3121	8.6	(-11.7,23.1)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Nausea

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.45, inf)	inf	(0.36, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Vomiting

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	2	5.7	1.8	110.0	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Vomiting

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Asthenia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	213.6	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Asthenia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.9	106.8	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	3	16.7	0.5	619.1	35	2	5.7	1.9	107.6	0.3121	-11.0 (-36.0,7.8)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.30	(0.03,2.29)	0.34	(0.04,2.00) (0.06,1.87)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Infections and infestations
Preferred term: Streptococcal infection

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Infections and infestations
Preferred term: Streptococcal infection

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	189.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Aspartate aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	189.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Aspartate aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Blood lactate dehydrogenase increased

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	212.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Blood lactate dehydrogenase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil count increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil count increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil percentage increased

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil percentage increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Haematocrit decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Haematocrit decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Haemoglobin decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Haemoglobin decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Platelet count increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	212.4	35	1	2.9	1.9	52.6	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Platelet count increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Protein total decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Protein total decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Decreased appetite

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Decreased appetite

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Hyperuricaemia

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	192.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Hyperuricaemia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Joint swelling

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	189.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Joint swelling

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Myalgia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	194.3	35	1	2.9	1.9	52.8	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Myalgia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Pain in extremity

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	218.7	35	2	5.7	1.9	107.1	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Pain in extremity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	0.5	394.9	35	0	0.0	1.9	0.0	0.0829	-11.1 (-34.7,1.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,1.08)	0.00	(0.00,1.35)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	218.7	35	4	11.4	1.8	220.7	0.7740	5.9	(-17.0,22.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Paraesthesia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	196.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Paraesthesia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Anxiety

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	192.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Anxiety

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Respiratory, thoracic and mediastinal disorders
Preferred term: Cough

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Respiratory, thoracic and mediastinal disorders
Preferred term: Cough

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Alopecia

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	212.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Alopecia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Dermatitis allergic

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	213.6	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Dermatitis allergic

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.5	608.8	35	5	14.3	1.7	298.9	0.8862	-2.4	(-28.5,17.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.83	(0.17,4.76)	0.86	(0.22,7.46) (0.23,3.19)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Vascular disorders
Preferred term: Hypotension

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	220.0	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.8 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Vascular disorders
Preferred term: Hypotension

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Erythropenia

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	155.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Erythropenia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Cardiac disorders
Preferred term: Palpitations

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Cardiac disorders
Preferred term: Palpitations

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Nausea

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	3	8.6	4.6	65.1	0.3121	8.6	(-11.7,23.1)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Nausea

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.45, inf)	inf	(0.36, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Vomiting

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	2	5.7	4.6	43.6	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Gastrointestinal disorders
Preferred term: Vomiting

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Asthenia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	151.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Asthenia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.7	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	3	16.7	0.8	361.6	35	2	5.7	4.9	40.7	0.3121	-11.0 (-36.0,7.8)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.30	(0.03,2.29)	0.34	(0.04,2.00) (0.06,1.87)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Infections and infestations
Preferred term: Streptococcal infection

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Infections and infestations
Preferred term: Streptococcal infection

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	138.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Aspartate aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	138.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Aspartate aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Blood lactate dehydrogenase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	150.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Blood lactate dehydrogenase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil count increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil count increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil percentage increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Eosinophil percentage increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Haematocrit decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Haematocrit decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Haemoglobin decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Haemoglobin decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.2	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: High density lipoprotein increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Platelet count increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	150.9	35	1	2.9	4.8	20.8	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Platelet count increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Protein total decreased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	155.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Protein total decreased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Decreased appetite

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	155.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Decreased appetite

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Hyperuricaemia

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Metabolism and nutrition disorders
Preferred term: Hyperuricaemia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Joint swelling

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.5	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Joint swelling

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Myalgia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	116.3	35	1	2.9	4.8	20.8	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Myalgia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Pain in extremity

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.1	35	2	5.7	4.8	41.8	1.0000	0.2	(-21.9,15.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Pain in extremity

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.07,32.09)	1.03	(0.10,27.91) (0.10,10.59)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

	Placebo					Speso 900 mg IV SD						
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff. (95% CI)
Overall	18	2	11.1	0.9	234.9	35	0	0.0	5.0	0.0	0.0829	-11.1 (-34.7,1.4)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Dizziness

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,1.08)	0.00	(0.00,1.35)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.1	35	4	11.4	4.6	87.4	0.7740	5.9	(-17.0,22.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Headache

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	2.19	(0.25,57.28)	2.06	(0.30,52.13) (0.25,17.07)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Paraesthesia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	142.7	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Nervous system disorders
Preferred term: Paraesthesia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day
before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Anxiety

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Anxiety

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Respiratory, thoracic and mediastinal disorders
Preferred term: Cough

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Respiratory, thoracic and mediastinal disorders
Preferred term: Cough

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Alopecia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	150.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Alopecia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Dermatitis allergic

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	151.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Dermatitis allergic

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	3	16.7	0.8	358.1	35	6	17.1	4.3	138.1	1.0000	0.5	(-25.6,21.2)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.22,5.69)	1.03	(0.29,7.59) (0.29,3.64)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Vascular disorders
Preferred term: Hypotension

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.6	154.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.9 Proportion and incidence rate of patients with adverse events with mild maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Vascular disorders
Preferred term: Hypotension

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Anaemia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Anaemia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	299.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Hepatobiliary disorders
Preferred term: Hepatic function abnormal

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	292.2	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Hepatobiliary disorders
Preferred term: Hepatic function abnormal

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	294.6	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Insomnia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	294.6	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Insomnia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pain of skin

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	297.0	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pain of skin

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	619.1	35	4	11.4	0.6	649.3	1.0000	0.3	(-24.0,18.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.10 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.03	(0.16,8.79)	1.03	(0.19,7.65) (0.21,5.09)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Anaemia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	195.3	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Anaemia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	193.3	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Hepatobiliary disorders
Preferred term: Hepatic function abnormal

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	190.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Hepatobiliary disorders
Preferred term: Hepatic function abnormal

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	191.2	35	1	2.9	1.9	51.5	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: C-reactive protein increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.5	0.0	35	2	5.7	1.8	109.2	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Investigations
Preferred term: C-reactive protein increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Arthralgia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	212.4	35	1	2.9	1.9	53.2	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Arthralgia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Insomnia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	191.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Insomnia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pain of skin

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	192.2	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pain of skin

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.5	394.9	35	5	14.3	1.8	282.7	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.11 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Anaemia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	116.7	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Blood and lymphatic system disorders
Preferred term: Anaemia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Inflammation

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	132.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Inflammation

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	116.0	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Oedema peripheral

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Hepatobiliary disorders
Preferred term: Hepatic function abnormal

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	114.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Hepatobiliary disorders
Preferred term: Hepatic function abnormal

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Injury, poisoning and procedural complications
Preferred term: Tendon injury

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	131.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Injury, poisoning and procedural complications
Preferred term: Tendon injury

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.2	35	1	2.9	4.9	20.6	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: Alanine aminotransferase increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: C-reactive protein increased

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.6	43.4	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Investigations
Preferred term: C-reactive protein increased

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Arthralgia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.7	150.9	35	1	2.9	4.9	20.3	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Arthralgia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Joint effusion

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	132.8	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Joint effusion

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Osteoarthritis

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	131.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Osteoarthritis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Tendonitis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	132.8	35	1	2.9	4.8	20.7	0.7741	-2.7	(-24.4,11.7)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Musculoskeletal and connective tissue disorders
Preferred term: Tendonitis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.50	(0.01,20.60)	0.51	(0.02,17.09) (0.03,7.75)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Insomnia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.2	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Psychiatric disorders
Preferred term: Insomnia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pain of skin

	Placebo					Speso 900 mg IV SD							
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	Speso 900 mg IV SD vs Placebo p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.9	115.6	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pain of skin

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	0	0.0	0.9	0.0	35	2	5.7	4.8	41.6	0.4283	5.7	(-13.7,19.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	inf	(0.24, inf)	inf	(0.20, inf)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.9	234.9	35	6	17.1	4.5	132.3	0.7741	6.0	(-19.1,25.6)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.66	(0.31,13.00)	1.54	(0.36,17.09) (0.35,6.89)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Urticaria

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	126.4	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.12 Proportion and incidence rate of patients with adverse events with moderate maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Urticaria

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.3	304.4	35	0	0.0	0.7	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.3	635.2	35	5	14.3	0.6	830.1	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.13 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.5	221.4	35	0	0.0	1.9	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.4	456.6	35	5	14.3	1.7	293.6	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.14 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	1	5.6	0.8	131.9	35	0	0.0	5.0	0.0	0.3093	-5.6	(-27.3,5.5)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
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Table 1.6.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: General disorders and administration site conditions
Preferred term: Pyrexia

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	0.00	(0.00,4.63)	0.00	(0.00,7.46)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

	Placebo					Speso 900 mg IV SD					Speso 900 mg IV SD vs Placebo		
Subgroup Category	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	N	n	%	Time at risk [pt-yrs]	Rate/100 pt-yrs	p-value*	Risk diff.	(95% CI)
Overall	18	2	11.1	0.7	268.6	35	5	14.3	4.3	115.6	0.8734	3.2	(-21.3,21.9)

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.15 Proportion and incidence rate of patients with adverse events with severe maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)
System organ class: Skin and subcutaneous tissue disorders
Preferred term: Pustular psoriasis

Subgroup Category	Speso 900 mg IV SD vs Placebo				
	Odds ratio	(95% CI)	Risk ratio	(exact 95% CI) (asymp 95% CI)	p-value**
Overall	1.33	(0.23,10.83)	1.29	(0.27,9.91) (0.28,5.99)	

Subgroups for analyses by SOC and PT are not displayed because overall test for treatment is not significant on 5% level

N is the number of patients in the respective analysis set. n is the number of patients with at least one event in the respective analysis set.
Patients with AE:Time at risk=start of first AE-start of treatment+1. Patients without AE:time at risk=end of time at risk-start of treatment+1.
End of time at risk: min of (the day before any non-randomized Speso, Day 6, the day of EoS if pts were not rolled over or the day before first dose in OLE study if pts were rolled over). All AEs starting up to the end of time at risk are included.
Exact confidence intervals (CIs) for risk ratios and risk differences are estimated by Chan and Zhang and for odds ratios exact mid-p confidence limits.
Asymptotic confidence intervals (CIs) for risk ratios are Wald confidence limits.
*2*one-sided p value is calculated using Suissa-Shuster Z-pooled test. **Q-test for homogeneity of risk ratios (treatment by subgroup interaction).
Maximum intensity: If a patient has more than one AE only the worst is recorded.
MedDRA version: 24.0 inf=infinity. NC = not calculable

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Table 1.6.16 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 1 - SAF (OC)

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Table 1.6.17 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 4 - SAF (OC)

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Table 1.6.18 Proportion and incidence rate of patients with adverse events with life-threatening maximum intensity with >=5% occurrence in at least one treatment arm on PT level overall and by subgroup up to week 12 - SAF (OC)

---------- No data satisfied to be displayed ----------

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