Anhang 4-G: Ergänzende Daten zu den Studienteile OptIMMize-1 Teil 1 und OptIMMize-1 Teil 3

Inhaltsverzeichnis

Seite

Anhang 4-G1: OptIMMize-1 Teil 1 2
Anhang 4-G1.1: Demografische Charakteristika zu Baseline 2
Anhang 4-G1.2: Krankheitsspezifische Charakteristika zu Baseline 7
Anhang 4-G1.3: Patientendisposition 10
Anhang 4-G1.4: Psoriasis Area and Severity Index (PASI) 13
Anhang 4-G1.5: Unerwünschte Ereignisse (UE) 18
Anhang 4-G2: OptIMMize-1 Teil 3 26
Anhang 4-G2.1: Demografische Charakteristika zu Baseline 26
Anhang 4-G2.2: Krankheitsspezifische Charakteristika zu Baseline 31
Anhang 4-G2.3: Patientendisposition 34
Anhang 4-G2.4: Psoriasis Area and Severity Index (PASI) 37
Anhang 4-G2.5: Unerwünschte Ereignisse (UE) 42

Anhang 4-G1: OptIMMize-1 Teil 1

Anhang 4-G1.1: Demografische Charakteristika zu Baseline

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 4

TABLE 14.1__1.3

Demographic Characteristics
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=12)
Sex - n (%)	
FEMALE	7 (58.3)
MALE	5 (41.7)
Ethnicity - n (%)	
HISPANIC OR LATINO	2 (16.7)
NOT HISPANIC OR LATINO	10 (83.3)
Race - n (%)	
WHITE	6 (50.0)
BLACK OR AFRICAN AMERICAN	2 (16.7)
ASIAN	1 (8.3)
AMERICAN INDIAN/ALASKA NATIVE	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	1 (8.3)
OTHER	0
MULTIPLE	2 (16.7)
Age (year)	
n	12
Mean (SD)	14.8 (2.22)
Median	15.5
Min, Max	12, 17
Age (year) - n (%)	
12 - < 15	5 (41.7)
15 - < 18	7 (58.3)

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

170

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 4

TABLE 14.1__1.3

Demographic Characteristics
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=12)
Weight (kg)	
n	12
Mean (SD)	66.17 (13.656)
Median	66.85
Min, Max	47.6, 92.9
Weight (kg) - n (%)	
< 40	0
>= 40	12 (100)
Weight (kg) by Sex	
Female	
n	7
Mean (SD)	66.02 (14.759)
Median	66.50
Min, Max	47.6, 92.9
Female@ - n (%)	
< 40	0
>= 40	7 (100)

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.
@ Percentages based on the number of female or male subjects.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

171

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 4

TABLE 14.1__1.3

Demographic Characteristics
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=12)
Weight (kg) by Sex (Cont.)	
Male	
n	5
Mean (SD)	66.38 (13.638)
Median	68.50
Min, Max	52.1, 80.8
Male@ - n (%)	
< 40	0
>= 40	5 (100)
Height (cm)	
n	12
Mean (SD)	163.67 (8.909)
Median	163.20
Min, Max	149.4, 177.0
Body Mass Index (kg/m^2)	
n	12
Mean (SD)	24.745 (4.8255)
Median	25.106
Min, Max	16.96, 32.08
Body Mass Index (kg/m^2) - n (%)	
< 25	6 (50.0)
>= 25	6 (50.0)

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.
@ Percentages based on the number of female or male subjects.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

172

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 4 OF 4

TABLE 14.1__1.3

Demographic Characteristics
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=12)
Region - n (%)	
Europe	0
North America	12 (100)
Rest of World	0

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

Anhang 4-G1.2: Krankheitsspezifische Charakteristika zu Baseline

05MAR2025 17:46 <! m19977-ds.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.1__1.4

Disease History
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=12)
History of Psoriatic Arthritis - n (%)	
Yes	0
No	12 (100)
Duration of Plaque Psoriasis (in Years)	
n	12
Mean (SD)	6.62 (3.135)
Median	7.19
Min, Max	1.1, 11.8
Prior Biologic Psoriasis Therapy - n (%)	
Yes	0
No	12 (100)
Prior Systemic Psoriasis Therapy - n (%)	
Yes	0
No	12 (100)

Note: RZB = Risankizumab.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-ds.sas

174

05MAR2025 17:46 <! m19977-ds.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.1__1.4

Disease History
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=12)
PASI (Psoriasis Area and Severity Index)	
n	12
Mean (SD)	21.43 (8.124)
Median	20.20
Min, Max	13.1, 38.0
BSA (Body Surface Area)	
n	12
Mean (SD)	21.92 (17.101)
Median	16.00
Min, Max	13.0, 75.0
sPGA categories - n (%)	
0	0
1	0
2	0
3	0
4	12 (100)

Note: RZB = Risankizumab.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-ds.sas

175

Anhang 4-G1.3: Patientendisposition

05MAR2025 17:46 <! m19977-disp.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.1__1.2

Subject Disposition
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Status	RZB (N=12) n (%)
Enrolled	
Never received any study drug	0
Received study drug	12 (100)
Completed Study	12 (100)
Discontinued Study	0
All Reasons for Discontinuation$	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0
Primary Reason for Discontinuation	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0

Note: RZB = Risankizumab.
$ Subjects who discontinued study or study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-disp.sas

168

05MAR2025 17:46 <! m19977-disp.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.1__1.2

Subject Disposition
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Status	RZB (N=12) n (%)
Discontinued Study Drug	0
All Reasons for Discontinuation$	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0
Primary Reason for Discontinuation	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0

Note: RZB = Risankizumab.
$ Subjects who discontinued study or study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-disp.sas

169

Anhang 4-G1.4: Psoriasis Area and Severity Index (PASI)

05MAR2025 17:52 <! m19977-nri-ao.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__1.2.1

Proportion of Subjects Achieving PASI 75 (NRI) by Visit
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Time Point Treatment	N	Responder n (%)	 [95% CI]$	Missing n (%)
WEEK 4				
RZB	12	4 (33.3)	[9.9, 65.1]	0
WEEK 8				
RZB	12	11 (91.7)	[61.5, 99.8]	0
WEEK 12				
RZB	12	11 (91.7)	[61.5, 99.8]	0
WEEK 16				
RZB	12	10 (83.3)	[51.6, 97.9]	0
WEEK 28				
RZB	12	11 (91.7)	[61.5, 99.8]	0
WEEK 40				
RZB	12	12 (100)	[73.5, 100.0]	0
WEEK 52				
RZB	12	12 (100)	[73.5, 100.0]	0

Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
$ Exact Clopper-Pearson CI for proportions.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-nri-ao.sas

306

05MAR2025 17:52 <! m19977-nri-ao.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__1.4.1

Proportion of Subjects Achieving PASI 90 (NRI) by Visit
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Time Point Treatment	N	Responder n (%)	 [95% CI]$	Missing n (%)
WEEK 4				
RZB	12	1 (8.3)	[0.2, 38.5]	0
WEEK 8				
RZB	12	7 (58.3)	[27.7, 84.8]	0
WEEK 12				
RZB	12	10 (83.3)	[51.6, 97.9]	0
WEEK 16				
RZB	12	10 (83.3)	[51.6, 97.9]	0
WEEK 28				
RZB	12	10 (83.3)	[51.6, 97.9]	0
WEEK 40				
RZB	12	11 (91.7)	[61.5, 99.8]	0
WEEK 52				
RZB	12	10 (83.3)	[51.6, 97.9]	0

Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
$ Exact Clopper-Pearson CI for proportions.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-nri-ao.sas

312

05MAR2025 17:52 <! m19977-nri-ao.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__1.5.1

Proportion of Subjects Achieving PASI 100 (NRI) by Visit
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Time Point Treatment	N	Responder n (%)	Responder [95% CI]$	Missing n (%)
WEEK 4				
RZB	12	0	[0.0, 26.5]	0
WEEK 8				
RZB	12	3 (25.0)	[5.5, 57.2]	0
WEEK 12				
RZB	12	6 (50.0)	[21.1, 78.9]	0
WEEK 16				
RZB	12	5 (41.7)	[15.2, 72.3]	0
WEEK 28				
RZB	12	8 (66.7)	[34.9, 90.1]	0
WEEK 40				
RZB	12	9 (75.0)	[42.8, 94.5]	0
WEEK 52				
RZB	12	8 (66.7)	[34.9, 90.1]	0

Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
$ Exact Clopper-Pearson CI for proportions.

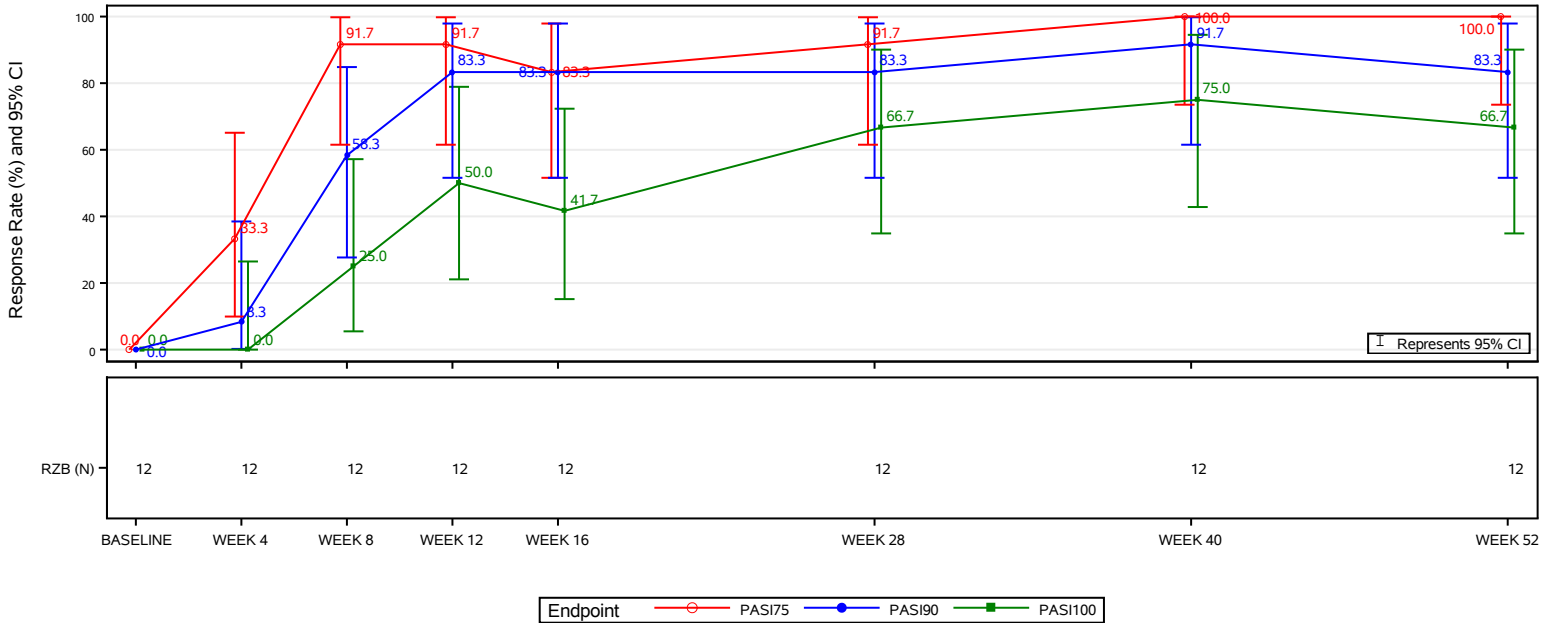
Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-nri-ao.sas

314

05MAR2025 19:38 <! m19977-prop-fig.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__1.1f

PASI75/90/100 Response Rate (NRI) and 95% CI by Visit
Part 1 (12 to <18 Years, Severe Disease)
(Intent to Treat (ITT) Population)



Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
Exact Clopper-Pearson CI for proportions.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-prop-fig.sas

563

Anhang 4-G1.5: Unerwünschte Ereignisse (UE)

05MAR2025 18:09 <! m19977-aeov.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.1.1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

	RZB (N=12) n (%)
Subjects with any treatment-emergent	
Adverse event (AE)	6 (50.0)
AE related to study drugs according to the investigator	0
Severe AE	0
Serious AE	0
AE leading to discontinuation of study drug	0
Serious infections	0
Opportunistic infection excluding tuberculosis and herpes zoster	0
Active tuberculosis	0
Herpes zoster	0
Malignant tumours	0
Malignant tumours excluding NMSC	0
Non-melanoma skin cancer (NMSC)	0
Hepatic event	1 (8.3)
Serious hypersensitivity	0
Injection site reaction	0
Adjudicated anaphylactic reaction	0
Suicidal ideation behavior (SIB)	0
AE leading to death	0
All deaths	0
Deaths occurring <= 140 days after last dose of study drug	0
Deaths occurring > 140 days after last dose of study drug	0

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aeov.sas

617

05MAR2025 18:09 <! m19977-ae.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3__1.1.2.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term	RZB (N=12) n (%)
Any adverse event	6 (50.0)
Gastrointestinal disorders	1 (8.3)
Abdominal pain	1 (8.3)
General disorders and administration site conditions	2 (16.7)
Chills	1 (8.3)
Pain	1 (8.3)
Pyrexia	2 (16.7)
Hepatobiliary disorders	1 (8.3)
Hypertransaminasaemia	1 (8.3)
Infections and infestations	4 (33.3)
Body tinea	1 (8.3)
COVID-19	1 (8.3)
Skin candida	1 (8.3)
Upper respiratory tract infection	1 (8.3)
Urinary tract infection	1 (8.3)
Injury, poisoning and procedural complications	1 (8.3)
Skin injury	1 (8.3)
Musculoskeletal and connective tissue disorders	1 (8.3)
Pain in extremity	1 (8.3)
Nervous system disorders	2 (16.7)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-ae.sas

631

05MAR2025 18:09 <! m19977-ae.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3__1.1.2.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term	RZB (N=12) n (%)
Nervous system disorders (Cont.)	
Headache	2 (16.7)
Reproductive system and breast disorders	1 (8.3)
Vulvovaginal pruritus	1 (8.3)
Skin and subcutaneous tissue disorders	1 (8.3)
Post inflammatory pigmentation change	1 (8.3)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-ae.sas

632

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 4

TABLE 14.3__1.1.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=12) n (%)
Any adverse event	6 (50.0)
Grade 1	5 (41.7)
Grade 2	1 (8.3)
Gastrointestinal disorders	1 (8.3)
Grade 1	1 (8.3)
Abdominal pain	1 (8.3)
Grade 1	1 (8.3)
General disorders and administration site conditions	2 (16.7)
Grade 1	1 (8.3)
Grade 2	1 (8.3)
Chills	1 (8.3)
Grade 1	1 (8.3)
Pain	1 (8.3)
Grade 2	1 (8.3)
Pyrexia	2 (16.7)
Grade 1	2 (16.7)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

641

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 4

TABLE 14.3__1.1.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=12) n (%)
Hepatobiliary disorders	1 (8.3)
Grade 1	1 (8.3)
Hypertransaminasaemia	1 (8.3)
Grade 1	1 (8.3)
Infections and infestations	4 (33.3)
Grade 1	3 (25.0)
Grade 2	1 (8.3)
Body tinea	1 (8.3)
Grade 1	1 (8.3)
COVID-19	1 (8.3)
Grade 1	1 (8.3)
Skin candida	1 (8.3)
Grade 2	1 (8.3)
Upper respiratory tract infection	1 (8.3)
Grade 1	1 (8.3)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

642

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 4

TABLE 14.3__1.1.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=12) n (%)
Infections and infestations (Cont.)	
Urinary tract infection	1 (8.3)
Grade 2	1 (8.3)
Injury, poisoning and procedural complications	1 (8.3)
Grade 1	1 (8.3)
Skin injury	1 (8.3)
Grade 1	1 (8.3)
Musculoskeletal and connective tissue disorders	1 (8.3)
Grade 1	1 (8.3)
Pain in extremity	1 (8.3)
Grade 1	1 (8.3)
Nervous system disorders	2 (16.7)
Grade 1	2 (16.7)
Headache	2 (16.7)
Grade 1	2 (16.7)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

643

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 4 OF 4

TABLE 14.3__1.1.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 1 (12 to <18 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=12) n (%)
Reproductive system and breast disorders	1 (8.3)
Grade 2	1 (8.3)
Vulvovaginal pruritus	1 (8.3)
Grade 2	1 (8.3)
Skin and subcutaneous tissue disorders	1 (8.3)
Grade 1	1 (8.3)
Post inflammatory pigmentation change	1 (8.3)
Grade 1	1 (8.3)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

644

Anhang 4-G2: OptIMMize-1 Teil 3

Anhang 4-G2.1: Demografische Charakteristika zu Baseline

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 4

TABLE 14.1__3.3

Demographic Characteristics
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=13)
Sex - n (%)	
FEMALE	9 (69.2)
MALE	4 (30.8)
Ethnicity - n (%)	
HISPANIC OR LATINO	1 (7.7)
NOT HISPANIC OR LATINO	12 (92.3)
Race - n (%)	
WHITE	10 (76.9)
BLACK OR AFRICAN AMERICAN	0
ASIAN	3 (23.1)
AMERICAN INDIAN/ALASKA NATIVE	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0
OTHER	0
MULTIPLE	0
Age (year)	
n	13
Mean (SD)	9.7 (1.55)
Median	10.0
Min, Max	7, 11
Age (year) - n (%)	
6 - < 9	3 (23.1)
9 - < 12	10 (76.9)

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

249

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 4

TABLE 14.1__3.3

Demographic Characteristics
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=13)
Weight (kg)	
n	13
Mean (SD)	44.97 (14.612)
Median	41.20
Min, Max	24.5, 71.9
Weight (kg) - n (%)	
< 40	5 (38.5)
>= 40	8 (61.5)
Weight (kg) by Sex	
Female	
n	9
Mean (SD)	44.40 (15.791)
Median	40.00
Min, Max	24.5, 71.9
Female@ - n (%)	
< 40	4 (44.4)
>= 40	5 (55.6)

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.
@ Percentages based on the number of female or male subjects.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

250

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 4

TABLE 14.1__3.3

Demographic Characteristics
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=13)
Weight (kg) by Sex (Cont.)	
Male	
n	4
Mean (SD)	46.26 (13.634)
Median	48.25
Min, Max	29.4, 59.1
Male@ - n (%)	
< 40	1 (25.0)
>= 40	3 (75.0)
Height (cm)	
n	13
Mean (SD)	142.38 (13.512)
Median	142.24
Min, Max	123.0, 160.0
Body Mass Index (kg/m^2)	
n	13
Mean (SD)	22.302 (7.2089)
Median	22.579
Min, Max	14.83, 39.10
Body Mass Index (kg/m^2) - n (%)	
< 25	8 (61.5)
>= 25	5 (38.5)

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.
@ Percentages based on the number of female or male subjects.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

251

05MAR2025 17:46 <! m19977-dm.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 4 OF 4

TABLE 14.1__3.3

Demographic Characteristics
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=13)
Region - n (%)	
Europe	8 (61.5)
North America	5 (38.5)
Rest of World	0

Note: RZB = Risankizumab.
Percentages calculated on non-missing values.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-dm.sas

252

Anhang 4-G2.2: Krankheitsspezifische Charakteristika zu Baseline

05MAR2025 17:46 <! m19977-ds.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.1__3.4

Disease History
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=13)
History of Psoriatic Arthritis - n (%)	
Yes	1 (7.7)
No	12 (92.3)
Duration of Plaque Psoriasis (in Years)	
n	13
Mean (SD)	3.39 (2.083)
Median	3.22
Min, Max	0.7, 7.4
Prior Biologic Psoriasis Therapy - n (%)	
Yes	0
No	13 (100)
Prior Systemic Psoriasis Therapy - n (%)	
Yes	4 (30.8)
No	9 (69.2)

Note: RZB = Risankizumab.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-ds.sas

253

05MAR2025 17:46 <! m19977-ds.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.1__3.4

Disease History
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

	RZB (N=13)
PASI (Psoriasis Area and Severity Index)	
n	13
Mean (SD)	26.21 (9.158)
Median	23.40
Min, Max	17.0, 45.1
BSA (Body Surface Area)	
n	13
Mean (SD)	32.15 (18.443)
Median	24.00
Min, Max	10.0, 66.0
sPGA categories - n (%)	
0	0
1	0
2	0
3	2 (15.4)
4	11 (84.6)

Note: RZB = Risankizumab.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-ds.sas

254

Anhang 4-G2.3: Patientendisposition

05MAR2025 17:46 <! m19977-disp.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.1__3.2

Subject Disposition
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Status	RZB (N=13) n (%)
Enrolled	
Never received any study drug	0
Received study drug	13 (100)
Completed Study	13 (100)
Discontinued Study	0
All Reasons for Discontinuation$	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0
Primary Reason for Discontinuation	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0

Note: RZB = Risankizumab.
$ Subjects who discontinued study or study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-disp.sas

247

05MAR2025 17:46 <! m19977-disp.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.1__3.2

Subject Disposition
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Status	RZB (N=13) n (%)
Discontinued Study Drug	0
All Reasons for Discontinuation$	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0
Primary Reason for Discontinuation	
ADVERSE EVENT	0
WITHDREW CONSENT	0
LOST TO FOLLOW-UP	0
COVID-19 INFECTION	0
COVID-19 LOGISTICAL RESTRICTIONS	0
OTHER	0

Note: RZB = Risankizumab.
$ Subjects who discontinued study or study drug are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.1/PCMS_RUN/m19977-disp.sas

248

Anhang 4-G2.4: Psoriasis Area and Severity Index (PASI)

05MAR2025 17:52 <! m19977-nri-ao.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__3.2.1

Proportion of Subjects Achieving PASI 75 (NRI) by Visit
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Time Point Treatment	N	Responder n (%)	 [95% CI]$	Missing n (%)
WEEK 4				
RZB	13	4 (30.8)	[9.1, 61.4]	0
WEEK 8				
RZB	13	11 (84.6)	[54.6, 98.1]	0
WEEK 12				
RZB	13	12 (92.3)	[64.0, 99.8]	0
WEEK 16				
RZB	13	12 (92.3)	[64.0, 99.8]	0
WEEK 28				
RZB	13	13 (100)	[75.3, 100.0]	0
WEEK 40				
RZB	13	13 (100)	[75.3, 100.0]	0
WEEK 52				
RZB	13	13 (100)	[75.3, 100.0]	0

Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
$ Exact Clopper-Pearson CI for proportions.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-nri-ao.sas

467

05MAR2025 17:52 <! m19977-nri-ao.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__3.4.1

Proportion of Subjects Achieving PASI 90 (NRI) by Visit
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Time Point Treatment	N	Responder n (%)	 [95% CI]$	Missing n (%)
WEEK 4				
RZB	13	0	[0.0, 24.7]	0
WEEK 8				
RZB	13	7 (53.8)	[25.1, 80.8]	0
WEEK 12				
RZB	13	10 (76.9)	[46.2, 95.0]	0
WEEK 16				
RZB	13	11 (84.6)	[54.6, 98.1]	0
WEEK 28				
RZB	13	12 (92.3)	[64.0, 99.8]	0
WEEK 40				
RZB	13	13 (100)	[75.3, 100.0]	0
WEEK 52				
RZB	13	11 (84.6)	[54.6, 98.1]	0

Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
$ Exact Clopper-Pearson CI for proportions.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-nri-ao.sas

473

05MAR2025 17:52 <! m19977-nri-ao.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.2__3.5.1

Proportion of Subjects Achieving PASI 100 (NRI) by Visit
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)

Time Point Treatment	N	Responder n (%)	Responder [95% CI]$	Missing n (%)
WEEK 4				
RZB	13	0	[0.0, 24.7]	0
WEEK 8				
RZB	13	3 (23.1)	[5.0, 53.8]	0
WEEK 12				
RZB	13	4 (30.8)	[9.1, 61.4]	0
WEEK 16				
RZB	13	7 (53.8)	[25.1, 80.8]	0
WEEK 28				
RZB	13	8 (61.5)	[31.6, 86.1]	0
WEEK 40				
RZB	13	8 (61.5)	[31.6, 86.1]	0
WEEK 52				
RZB	13	9 (69.2)	[38.6, 90.9]	0

Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
$ Exact Clopper-Pearson CI for proportions.

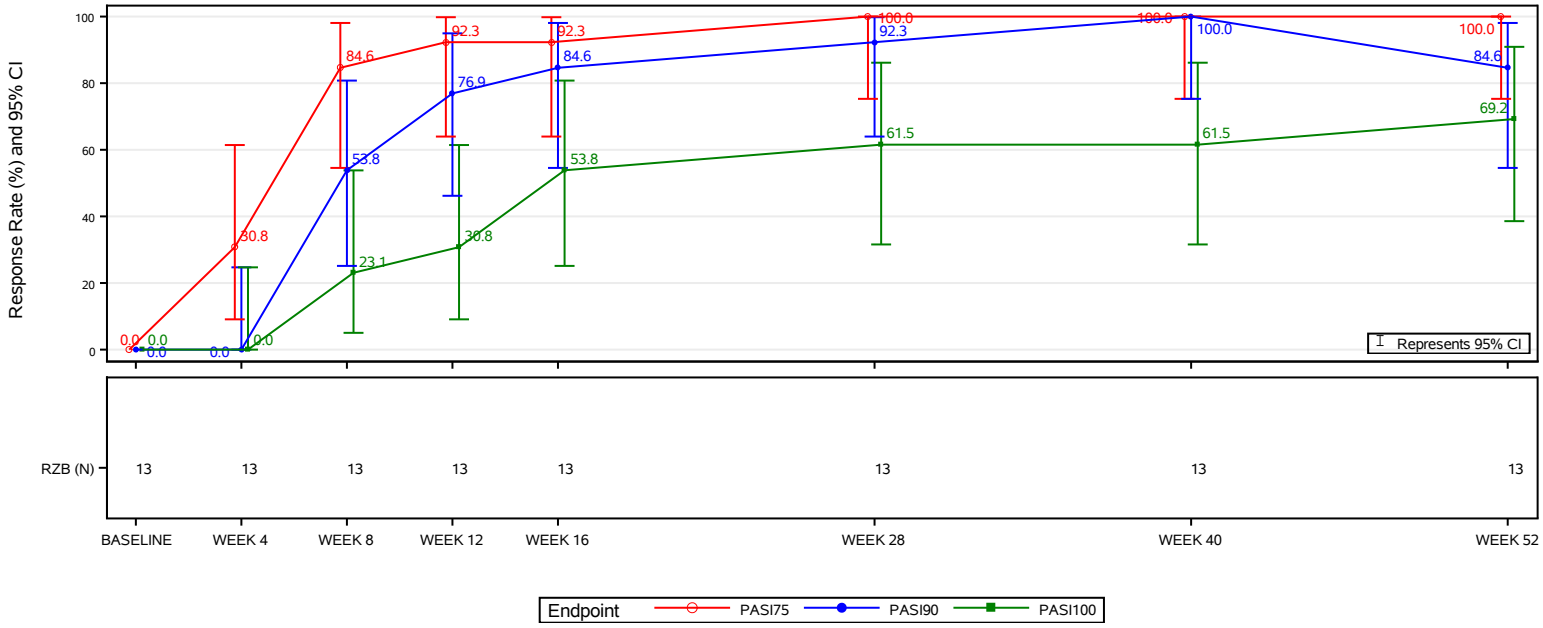
Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-nri-ao.sas

475

05MAR2025 19:38 <! m19977-prop-fig.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
FIGURE PAGE 1 OF 1

FIGURE 14.2__3.1f

PASI75/90/100 Response Rate (NRI) and 95% CI by Visit
Part 3 (6 to <12 Years, Severe Disease)
(Intent to Treat (ITT) Population)



Note: RZB = Risankizumab.
Non-Responder Imputation (NRI): the NRI analysis will categorize any subject who does not have evaluation during a specific post-baseline visit window as a non-responder for that visit. Values after the start of rescue medication are excluded from analysis and subjects are considered non-responders at all time points after the start of rescue medication.
Exact Clopper-Pearson CI for proportions.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.2/PCMS_RUN/m19977-prop-fig.sas

607

Anhang 4-G2.5: Unerwünschte Ereignisse (UE)

05MAR2025 18:09 <! m19977-aeov.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.3__1.3.1.1

Overview of Treatment-Emergent Adverse Events and All Deaths
Part 3 (6 to <12 Years, Severe Disease)
(Safety Analysis Population)

	RZB (N=13) n (%)
Subjects with any treatment-emergent	
Adverse event (AE)	6 (46.2)
AE related to study drugs according to the investigator	3 (23.1)
Severe AE	1 (7.7)
Serious AE	0
AE leading to discontinuation of study drug	0
Serious infections	0
Opportunistic infection excluding tuberculosis and herpes zoster	0
Active tuberculosis	0
Herpes zoster	0
Malignant tumours	0
Malignant tumours excluding NMSC	0
Non-melanoma skin cancer (NMSC)	0
Hepatic event	0
Serious hypersensitivity	0
Injection site reaction	0
Adjudicated anaphylactic reaction	0
Suicidal ideation behavior (SIB)	0
AE leading to death	0
All deaths	0
Deaths occurring <= 140 days after last dose of study drug	0
Deaths occurring > 140 days after last dose of study drug	0

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aeov.sas

835

05MAR2025 18:09 <! m19977-ae.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 2

TABLE 14.3__1.3.2.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Part 3 (6 to <12 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term	RZB (N=13) n (%)
Any adverse event	6 (46.2)
General disorders and administration site conditions	1 (7.7)
Pyrexia	1 (7.7)
Infections and infestations	6 (46.2)
Bronchitis	1 (7.7)
COVID-19	1 (7.7)
Conjunctivitis	1 (7.7)
Gastroenteritis viral	1 (7.7)
Lice infestation	1 (7.7)
Nasopharyngitis	1 (7.7)
Otitis media	1 (7.7)
Paronychia	1 (7.7)
Rhinitis	1 (7.7)
Upper respiratory tract infection	2 (15.4)
Investigations	1 (7.7)
Blood potassium increased	1 (7.7)
Metabolism and nutrition disorders	1 (7.7)
Vitamin D deficiency	1 (7.7)
Respiratory, thoracic and mediastinal disorders	2 (15.4)
Cough	2 (15.4)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-ae.sas

849

05MAR2025 18:09 <! m19977-ae.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 2

TABLE 14.3__1.3.2.1.1

Subjects with Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Part 3 (6 to <12 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term	RZB (N=13) n (%)
Respiratory, thoracic and mediastinal disorders (Cont.)	
Rhinorrhoea	1 (7.7)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-ae.sas

850

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 3

TABLE 14.3__1.3.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 3 (6 to <12 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=13) n (%)
Any adverse event	6 (46.2)
Grade 1	2 (15.4)
Grade 2	3 (23.1)
Grade 3	1 (7.7)
General disorders and administration site conditions	1 (7.7)
Grade 1	1 (7.7)
Pyrexia	1 (7.7)
Grade 1	1 (7.7)
Infections and infestations	6 (46.2)
Grade 1	3 (23.1)
Grade 2	3 (23.1)
Bronchitis	1 (7.7)
Grade 2	1 (7.7)
COVID-19	1 (7.7)
Grade 2	1 (7.7)
Conjunctivitis	1 (7.7)
Grade 1	1 (7.7)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

858

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 2 OF 3

TABLE 14.3__1.3.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 3 (6 to <12 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=13) n (%)
Infections and infestations (Cont.)	
Gastroenteritis viral	1 (7.7)
Grade 1	1 (7.7)
Lice infestation	1 (7.7)
Grade 2	1 (7.7)
Nasopharyngitis	1 (7.7)
Grade 2	1 (7.7)
Otitis media	1 (7.7)
Grade 2	1 (7.7)
Paronychia	1 (7.7)
Grade 2	1 (7.7)
Rhinitis	1 (7.7)
Grade 1	1 (7.7)
Upper respiratory tract infection	2 (15.4)
Grade 1	2 (15.4)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

859

05MAR2025 18:09 <! m19977-aesev.sas >
RISANKIZUMAB (PSORIASIS)
STUDY M19-977 - FINAL ANALYSIS
R&D/23/2034 - CLINICAL/STATISTICAL
TABLE PAGE 3 OF 3

TABLE 14.3__1.3.4

Subjects with Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity
Part 3 (6 to <12 Years, Severe Disease)
(Safety Analysis Population)

MedDRA 27.0 System Organ Class Preferred Term Severity	RZB (N=13) n (%)
Investigations	1 (7.7)
Grade 3	1 (7.7)
Blood potassium increased	1 (7.7)
Grade 3	1 (7.7)
Metabolism and nutrition disorders	1 (7.7)
Grade 1	1 (7.7)
Vitamin D deficiency	1 (7.7)
Grade 1	1 (7.7)
Respiratory, thoracic and mediastinal disorders	2 (15.4)
Grade 1	2 (15.4)
Cough	2 (15.4)
Grade 1	2 (15.4)
Rhinorrhoea	1 (7.7)
Grade 1	1 (7.7)

Note: RZB = Risankizumab.
Treatment-emergent adverse events (TEAEs) are defined as any event with an onset date that is on or after the first dose of study drug and within 140 days after the last dose of study drug.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.

Program Source Code: /SDA/ABBV-066/Psoriasis/CSR/M19-977/Final/14.3/PCMS_RUN/m19977-aesev.sas

860